AMERICAN COLLEGE OF CHEST PHYSICIANS

35

December 19, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1502FC and CMS-1325-F Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule

American College of Chest Physicians Comments address: SGR, Education and Training Codes, Supplemental Practice Expense Surveys, Respiratory Therapy G0237-G0239, Inhalation Drugs and Dispensing Fees, Missing Equipment Pricing Data

Dear Dr. McClellan:

I am submitting these comments on behalf of the American College of Chest Physicians (ACCP). The ACCP is comprised of over 16,500 physicians and allied health professionals, whose everyday practice involves disease of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, sleep and anesthesiology. These health care professionals practice in virtually every hospital in this country, and many of the physicians head major departments in these hospitals. As a multidisciplinary society, the ACCP offers broad viewpoints on matters of public health and clinical policy in cardiopulmonary medicine and surgery. The ACCP appreciates the opportunity to submit comments for consideration on the CMS final rule regarding Medicare's Revisions to Payment Policies under the Physician Fee Schedule for CY 2006 published on November 21, 2005. III. In addition, ACCP applauds CMS efforts to increase communication through monthly conference calls and through their newly formatted and informative CMS Web site.

3300 Dundee Road • Northbrook, Illinois 60062-2348 • USA
847/498-1400 *voice* • 847/498-5460 *fax* • accp@chestnet.org *e-mail*
www.chestnet.org

I. SUSTAINABLE GROWTH RATE (SGR) FORMULA AND P4P

Every medical specialty agrees that the SGR formula needs to be abolished and replaced with annual updates based on the Medicare Economic Index. With the aging of the US population, early retirement of health care providers, and a broken reimbursement formula, patient care is already being compromised. We cannot continue to work with the usual minor fixes and delays. We need to permanently fix this problem in order to ensure quality care.

Until the problem with the SGR is fixed, ACCP strongly urges CMS to exercise its discretionary authority to remove the costs of Medicare-covered physician-administered drugs from the SGR calculation, which have increased from $1.8 billion in 1996 to $8.7 billion in 2004. Nearly the entire medical community has commented on this issue and continues to remain frustrated that this SGR-adjustment has not been made.

ACCP agrees with the AMA position that physicians cannot support any "Value-based purchasing" or "Pay for Performance" initiatives as proposed by CMS. The 36 measures that CMS has put forward have not been reviewed by all involved medical specialties and yet CMS requests that these be implemented in 2006. In addition, electronic claims processing programs used by most medical practices are not programmed to report these measures. They are only currently programmed to report CPT 5 digit codes with attached dollar amounts.

ACCP also agrees that CMS should work with the long-established AMA Performance Measures Advisory Group, in which we actively participate, to review, evaluate, and develop proper educational programs for medical specialties in order to implement a value based purchasing initiative .

ACCP also requests that additional monies be added to the Medicare Physician Fee Schedule to support the ancillary costs associated with new preventive care benefits that have been recently added for beneficiaries.

II. RESPIRATORY THERAPY "G" CODES TRANSITIONING TO CPT (page 70150)

We are requesting that respiratory therapy be a covered benefit, and RT services be valued equivalent to the same service provided by PT/OT. ACCP is frustrated by the continued resistance of CMS to support services provided by respiratory therapists, when the same service, if provided by a physical or occupational therapist, is supported at nearly double the payment by CPT code 97110. ACCP has scheduled a meeting with CMS for January 24, 2006 to discuss this issue. A CPT proposal is scheduled for review in February 2006 by the CPT Editorial Panel to transition three G codes, G0237-G0239, into CPT codes. Maintaining the old "profiling" system from 1992 would impact reimbursement for RT's, and hinder specialty societies from getting codes approved in CPT, and valued in RUC, which would be recognized by other third party payers.

We are looking forward to the opportunity for this discussion. ACCP, as part of a group of specialties, submitted a request to CMS for a National Coverage Decision on April 3, 2003, and

to date have not had a response to our request on this issue. We understand that there are rules regarding a time limit in responding to such requests. We are long past that time limit.

III. EDUCATION AND TRAINING CODES REQUEST FOR COVERAGE

The ACCP requests that CMS reconsider their decision to not cover the new Education and Training codes, CPT 98960-98962 for Patient Self-Management by non-physician health care professionals. Physician education is appropriately included and reported in an evaluation and management code. These codes were developed by specialties who care for patients diagnosed with diabetes and asthma. These codes are used to report educational and training services prescribed by a physician and provided by a qualified, non-physician healthcare professional using a standardized curriculum to an individual or group of patients for the treatment of established illness(s)/disease(s) or to delay comorbidity(s).

CMS actively participated in the process of dividing the group code into two codes so that the practice expenses could be accurately calculated. We were surprised to see that these codes were not covered. We ask your reconsideration of this issue and offer to meet with you to discuss this benefit for your beneficiaries. Education is key to assisting our patients, your beneficiaries, in understanding their illness and the importance of medication compliance. If you continue to choose not to cover these codes, we ask that you publish the relative values for the codes so that other insurers would know the values, since the RUC database is proprietary and not available to other third party insurers. There is CMS precedence in reporting such values with other preventive services.

IV. SUPPLEMENTAL PRACTICE EXPENSE SURVEYS (pages 70132-70133)

We believe that CMS should incur the costs of an all physician practice expense survey, and not transfer any additional costs to AMA and other specialties. We are sure that those specialties that have already individually spent at least $30,000 for a supplemental survey will not want to share in any additional costs of an all-physician survey.

We applaud CMS' honesty in reporting their practice expense calculation error for indirect costs. ACCP requests CMS to continue with the transition to the bottom up PE methodology, instead of the current top-down PE methodology for direct costs.

V. PAYMENT FOR INHALATION DRUGS AND DISPENSING FEE (page 70225-70233)

ACCP notes the decision documented on page 70229: …Thus beginning in 2006, we will pay a dispensing fee of $57 for the first month an individual uses inhalation drugs as a Medicare Beneficiary, and $33 for a 30-day supply of inhalation drugs for all other months, and on page 70230… establishing a fee of $66 for a 90-day supply of inhalation drugs for 2006.

CMS provided no data for their rationale in reducing the fee to $33 for months after the first month, and for reducing the 90-day supply fee from $80 to $66. We ask that this be closely monitored. We expect that the 90-day supply will become the dispensing method of choice after the first trial month. If the patient is non-compliant or the medication is not working during that second month, the physician might prescribe an additional drug(s), which could potentially waste expensive medication which has already been reimbursed.

The College participated in a CMS conference call on December 16, 2005, for preliminary discussions with your research staff on development of a demonstration project related to the fee structure on inhalation drug dispensing. It was quite an informative call and we look forward to continued discussions as CMS develops this demonstration project.

VI. SUPPLIES AND EQUIPMENT REQUESTS

Regarding Table 14, Supply Items Needing Specialty Input for Pricing-Page 70144, SA091, we have already provided the tray contents to Pam West at CMS, which supports pricing the tray at $750.

Table 15 Equipment Items Needing Specialty Input for Pricing and Proposed Deletions (page 70145, 70147)

Code	Description	Price	Specialty	CPT Codes Associated with Equipment
EQ131	Hyperbaric chamber	$125,000	FP, IM, EM	99183
EQ221	Review master	$23,500	Pulmonary disease, Neurology	95805, 95807-11, 95816, 95822, 95955-6

The College will provide information directly to Pam West on these two pieces of equipment. Sechrist Industries provided a quote for the hyperbaric chamber at $128,000 for a monochamber.

The ACCP appreciates the opportunity to comment on the proposed policies under the Medicare Physician Fee Schedule. Should you or your staff have any questions, please do not hesitate to contact me, or Lynne Marcus at lmarcus@chestnet.org. Her telephone number is (847) 498-8331.

Sincerely,

W. Michael Alberts, MD, FCCP
President

Attachment: Monoplace Hyperbaric System Costs
Cc: ACCP Practice Management Committee
ACCP Government Relations Committee

SECHRIST
Industries, Inc.

4225 E. La Palma Ave.
Anaheim, CA 92807
Phone: 714-579-8400
Fax: 714-579-0814
Website: SechristUSA.com

QUOTE TO:

Diane Krier-Morrow
CPT and RUC Staff for ACCP and ATS

Phone: 847-677-9464
E-mail: DKRIERMORR@aol.com

QUOTATION NUMBER: 05-0771R2
QUOTATION VALID: 30 Days
PREPARED BY: Brianna Brunner
STANDARD TERMS: 30% Down with P.O.
50% Prior to Shipment
20% Net 30 Days
EX FACTORY: Anaheim, CA.
SHIP VIA: Prepaid truck. Add to invoice
DELIVERY: Subject to Availability
QUOTATION DATE: 12/19/05

Qty	Part No.	Description	Price Each	Ext. Price
1	3200	Monoplace Hyperbaric System, 32" Diameter, Pneumatic Control Panel	$128,000.00	$128,000.00
		Chamber Subtotal		**$128,000.00**

Each chamber comes complete with the following:

1	21464	Standard Gurney Assembly with Deluxe Wide Patient Stretcher and Mattress	N/C	N/C
1	23051	Patient Call Assembly	N/C	N/C
1	21345	Accessory Mount Assembly	N/C	N/C
1	35243	19 Pin Electrical Port – door side hull	N/C	N/C
1	22156	19 Pin Patient Cable – exterior to chamber	N/C	N/C
1	22157	19 Pin Patient Cable – interior of chamber	N/C	N/C
3	HB 228-IV	I.V. Pass Through Ports	N/C	N/C
1	20354	Cotton Cover	N/C	N/C
Lot	----	Non Stock Hoses and Adapters for Installation	N/C	N/C
Lot	----	Non Stock Spare Parts Kit	N/C	N/C
1	----	*Installation and Technical In-service Training*	N/C	N/C
		Subtotal (2) Chambers		$128,000.00
		Shipping Crates		$1,470.00
		Freight and Insurance		TBD
		Total (2) Chambers		**$129,470.00**

Option at time of Purchase:

Qty	Part No.	Description	Price Each	Ext. Price
	----	Upgrade Standard Gurney to Hydraulic Gurney with Deluxe Wide Patient Stretcher & Mattress (p/n 21465)	$3,050.00	

Maintenance Options:

----	Total Care™ Maintenance Agreement Annual preventative maintenance with 12 month service coverage. The agreement goes into effect after the warranty period.	$2,290.00
	or	
----	Preventative Maintenance Agreement Annual preventative maintenance only. This program offers a one-time yearly service during the time that one of our service technicians is in your area. Under this program, we offer a 30 day warranty period starting from the time the service has been performed.	$1,490.00

- **Tax has not been included in the quote, but does apply. If you are tax exempt, your tax exempt certificate must accompany your order.**
- All purchases are subject to standard terms, based on approved credit, unless other arrangements are made and agreed upon by Sechrist Industries.
- Acceptance of a purchase order will be based upon a written confirmation from Sechrist Industries, Inc. documenting the agreed upon terms of sale and is subject to final credit approval.
- Freight charges are based on current rates and tariffs and are subject to change.
- Prices are subject to change without notice.
- Parts and labor are warranted for one year from date of purchase.

By: _____

Caryn Oldham, U.S. Regional V.P. of Sales- Hyperbaric Systems
Toll-free: 800-732-4747 ext. 221
Direct: 714-579-8321
Cell: 714-322-6628
Fax: 714-579-0814
Email: coldham@sechristusa.com

UROLOGY ASSOCIATES OF SOUTHEASTERN NC, P.A.
1905 Glen Meade Road Wilmington, NC 28403

Phone: (910) 763-6251 **Fax: (910) 763-7408**

January 1, 2006

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

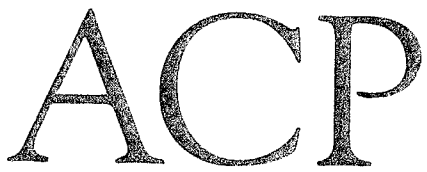
CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to ***all*** specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank You,

Robert V. Nichols, MD

Rec'd 1/4/06
37



AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

January 3, 2006

Mark B. McClellan, MD, PhD, FACP
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

File Code: CMS-1502-FC

Dear Dr. McClellan:

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS) final rule with comment: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B," published in the November 21, 2005 *Federal Register*. Our comments are listed under the topic headings as they appear in the final rule.

Payment for Covered Outpatient Drugs and Biologicals

Competitive Acquisition of Outpatient Drugs and Biologicals under Part B

ACP continues to appreciate the CMS efforts to develop the Competitive Acquisition Program (CAP) for Part B drugs and biologicals, which serves as an alternative to the current practice of physicians buying and billing for drugs under the average sales price (ASP) system. We are pleased that initial enrollment is anticipated to begin this spring with program start-up planned for July 1, 2006. However, the College continues to have concerns regarding the following features of the CAP that will have a significant affect on whether or not internists and medical subspecialists will participate in the program:

- The requirement for physicians to bill claims within 14 calendar days of the date a drug or biological acquired through the CAP was administered.

The College continues to take the position that this 14 calendar day billing requirement will impose an excessive burden in many practice settings, particularly within the small practice setting that provides care for the majority of our Medicare beneficiaries. Many practices continue

to rely significantly on manual, time consuming processes as part of their office-based billing processes, and additional delays are often encountered due to missing required billing information, such as the failure of a patient to bring an insurance card and simple clerical errors. Even the CMS data presented in this final rule indicated that 25 percent of physician claims are currently not filed within 14 days of service. As a result of this unreasonably short required filing time, many practitioners who may be interested in the CAP program will not participant. **ACP recommends that CMS establish, at a minimum, a 30 calendar day period to bill claims.** This time period better meets the needs of the typical practice, and at the same time recognizes the needs of the vendors who must wait for the claims to be submitted in order to bill CMS for the drugs or biologicals. In addition, the College recommends that the imposition of any penalty for late submission should be preceded by a reasonable warning protocol implemented by the carrier.

- The decision not to provide a separate or additional payment to cover the clerical and inventory resources associated with participation in the CAP.

The College continues to believe the CAP program will require the use of more clerical and inventory resources than under the ASP. These resources will be incurred because of activities such as needing to include additional information on drug order forms, having to repeatedly acquire drugs linked to each patient as opposed to more bulk purchasing, having to return drugs that are not administered, and having to appeal (or provide information in support of a vendor's appeal) a larger number of denials solely to ensure that the vendor receives payment. These increased administrative burdens without adequate compensation limit the attractiveness of the CAP program for many practices, particularly the smaller ones. **ACP recommends that CMS provide a payment to cover these additional administrative costs for CAP participation. At a minimum, we urge the agency to collect appropriate data to determine the actual administrative cost of participating in this program and implement necessary payment modifications as indicated.** We are encouraged by the CMS December 5, 2005 testimony to the Practicing Physicians Advisory Council (PPAC) indicating that the agency was continuing to monitor this issue.

- The critical importance of disseminating information about the CAP to the physician community.

The College recognizes that the CAP is radically different from the current ASP program for the purchasing of drugs and biologicals for Medicare beneficiaries. It offers an alternative for physicians who want to relinquish the responsibilities of purchasing drugs and biologicals, billing Medicare for them and collecting co-insurance from their patients. In order to ensure adequate penetration of this program throughout the physician community, it is critically important that CMS employ multiple communication channels at the local and national level to publicize the program's existence. In addition, CMS must make sure that adequate resources exist for physicians to obtain necessary information regarding the program's operations, policies, and administrative procedures to effectively participate in it. **ACP recommends that CMS work closely with ACP and the other physician organizations to help deliver this information.**

Establishment of Interim Work RVUs for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System Codes (HCPCS) for 2006

Education and Training for Patient Self-Management, CPT 98960-98961

ACP urges CMS to provide the rationale behind its determination that these services, the CPT codes for which are new for 2006, are not a Medicare-covered benefit, resulting in the agency assigning "N", meaning "non-covered," status in the fee schedule. ACP supports the comments made by the American Association of Clinical Endocrinologists (AACE) and the Joint Council on Allergy, Asthma, and Immunology (JCAAI) that these valuable services—describing education and training for patient self-management services prescribed by a physician and provided by a qualified non-physician health professional using a standardized curriculum—appear to fit the Medicare statutory benefit category of "incident-to" services. The College believes that a CMS explanation would allow a dialogue to ensure that the agency made the appropriate coverage decision.

Care Plan Oversight Services, CPT 99339-99340

ACP urges CMS to clarify its decision to assign the new CPT care plan oversight code, 99340, oversight services to a patient who resides in his or her home, a domiciliary, rest home (e.g. assisted living facility), 30 minutes or more, status "I", meaning "not valid for Medicare, Medicare uses another code for reporting." The College is unclear as to which code a physician should use to bill these services to Medicare since neither HCPCS G0181 nor G0182 pertain to a patient described by the new codes—a patient who is in the home, domiciliary, or rest home setting.

Issues Related to the Sustainable Growth Rate (SGR) Methodology

The ACP continues to request that CMS take action to help correct the flawed Sustainable Growth Rate (SGR) formula that has reduced payments for physician services by 4.4 percent in 2006 and is slated to reduce payments by a cumulative 26 percent from 2006-2011. The reductions mandated by the current SGR methodology will significantly interfere with the ability of physicians to maintain and improve the quality of care provided to Medicare beneficiaries and may likely force a number of practitioners to leave the field or decrease their willingness to accept Medicare patients. We believe the negative affects of the current SGR methodology most adversely impact physicians in small office settings—the type of setting that treats the majority of Medicare beneficiaries.

While we recognized that it takes an act of Congress to replace the SGR-related payment system with a more suitable system, we believe that there are several things that CMS can do to facilitate such a change. We are specifically requesting that CMS:

- Remove Medicare Part B drugs from the SGR formula both retroactively through 1996, and proactively.

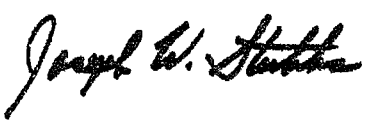
The removal of Medicare Part B drugs from the SGR formula, which we believe CMS has the administrative authority to do, would have the effect of decreasing the legislative cost of replacing the SGR and, thus, facilitate the likelihood that Congress will replace it. At a minimum, we urge CMS to remove these drugs proactively.

- Implement procedures to accurately track the effects of changes in Medicare Part A expenditures from changes made in the implementation of Part B services (e.g. quality improvement initiatives.)

The final rule discusses how hospital and physician services are currently paid for under separate systems. Thus, currently, there is no direct way to measure how improvements in the quality of care provided by physicians under Part B may results in saving to Medicare under Part A—through a reduction in costly emergency department visits and hospitalizations. Preliminary results of various CMS quality initiatives (e.g. Physician Group Practice demonstration), as well as the recent literature, support the likelihood of these savings. These savings could be used to cover the cost of replacing the SGR with a more suitable system. The CMS Physician Group Practice demonstration offers a potential model for implementing a means of tracking these savings.

ACP greatly appreciates this opportunity to comment on this final rule. Please do not hesitate to contact Brett Baker, Director, Regulatory and Insurer Affairs, at 202 261-4533 or bbaker@acponline.org or Neil Kirschner, Ph.D., Senior Associate, at 202 261-4535 or nkirschner@acponline.org if you have questions.

Sincerely,



Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee

UROLOGY ASSOCIATES OF SOUTHEASTERN NC, P.A.
1905 Glen Meade Road Wilmington, NC 28403

Phone: (910) 763-6251 **Fax: (910) 763-7408**

January 1, 2006

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to ***all*** specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank You,

Robert V. Nichols, MD

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

38 rec'd 1/4/06 5:05 PM

AdvaMed
Advanced Medical Technology Association

January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
Room 445–G, HHH Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, Final Rule with Comment, November 21, 2005 (CMS-1502-FC)

Dear Dr. McClellan,

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) Final Rule with Comment on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-FC, Federal Register, Vol. 70, No. 223, Monday, November 21, 2005, p. 70116).

AdvaMed is the largest medical technology trade association in the world, representing more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $71 billion health care technology products consumed annually in the United States, and nearly 50 percent of $169 billion purchased around the world annually.

In our comments below, we address the issue of practice expense relative value units (PE RVUs) for flow cytometry.

Flow Cytometry: Recent History of the Issue

In the final rule for the 2005 physician fee schedule published in the Federal Register on November 15, 2004, CMS published interim RVUs for revised flow cytometry codes, including the following two codes that are used for reporting the technical component of this important diagnostic test:

88184 Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker

88185 Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)

In the interim final rule, the PE RVUs and corresponding payments for these new codes were significantly reduced - more than 50% for the typical leukemia or lymphoma case - even though none of the revised RVUs were published for comment in the Proposed Rule. Of even greater concern was the fact that the coding changes were made without the benefit of the clinical expertise of the scientist in our member companies.

Working with representatives of independent laboratories and physician specialty societies, we reviewed the clinical staff, equipment and supply cost inputs used by CMS to determine the practice expense values for these services. Deficiencies in the CMS data were identified in three areas: 1) the costs associated with certain necessary instruments were missing; 2) the costs for the reagent antibodies were underestimated; and 3) the staff type that typically performs the test was incorrectly listed as a lab technician with a lower wage rate than the correct staff type of cytotechnologist. Requests to make corrections for the 2005 fee schedule were denied but in the proposed rule for 2006 that was published in the Federal Register on August 8, 2005, CMS proposed to accept the revised inputs. This contributed to proposed increases in the PE RVUs assigned to the two codes.

In the final rule for 2006 published in the Federal Register on November 21, 2005, CMS acknowledged widespread support for their proposal to revise the PE inputs as outlined above. However, while changes were made to the database, CMS published PE RVUs for these codes that are unchanged from 2005. As stated on page 70138 of the final rule the PE RVUs were not changed because "...we are making only limited, necessary changes to PE RVUs for the 2006 PFS."

Flow Cytometry: AdvaMed Response and Recommendations

We are extremely disappointed by the CMS decision to maintain the 2005 PE RVUs. We note that these codes were considered interim in 2005 and that comments were submitted immediately following publication of the final rule in hopes of obtaining a technical correction for 2005.

Some of our members were advised that a technical correction could not be made for 2005 but that the comments would be considered for the 2006 fee schedule. In accordance with this assurance, CMS proposed to accept the new inputs in the proposed rule for 2006. The CMS decision to not implement the proposed corrections is extremely troublesome in light of the facts that:

- the RVUs were interim in 2005;
- CMS proposed to make the necessary corrections in the 2006 proposed rule;
- CMS received and acknowledged the favorable responses to its proposal from all the major stakeholders; and,
- CMS revised its own database to reflect the revised inputs.

Under long-standing CMS policy, decisions on these interim codes should have been made final in this year's final rule. We understand, of course, that there are significant issues with the new practice expense methodology proposal, which has led to the intent to make only limited, necessary changes to PE RVUs for the 2006 PFS. However, because the issue with flow cytometry valuation extends back to the 2005 PFS, and CMS has not raised any technical issues related to the merit of making the proposed changes in the current rule, we believe the proposed changes should be made and reflected as though they were made at the beginning of 2005. This is not to say that we would expect retroactive, differential payment to providers for calendar year 2005, but we believe the only equitable solution is to increase the RVU's for 2006 per the proposed PFS rule based on the premise that, had the practice expense for the codes in question been properly valued in 2005, their PE RVU's would likewise have been extended as such into 2006, despite the practice expense freeze that is implemented in the current rule.

We respectfully recommend that CMS incorporate the revised PE inputs for the flow cytometry codes 88184 and 88185 into the calculation of the PE RVUs for 2006 and issue corrected values in a correction notice as soon as possible. We also ask that CMS work with the American Medical Association to open the CPT process, including the relative value updating committee (RUC) and practice expense advisory committee (PEAC) valuation processes, to the public since the codes that are created or revised through these CPT processes are used in the government's public programs of Medicare and Medicaid. The situation that occurred in 2004 when new codes and inputs were developed without the knowledge or input from patients, providers, clinical experts, and other stakeholders should not happen again.

We appreciate this opportunity to comment on the November 21, 2005 final rule and look forward to working with CMS to address our concerns. If you have any questions, please contact Teresa Lee, Associate Vice President, Payment & Policy at 202-434-7219

Sincerely,

David Nexon
Senior Executive Vice President

39

rec'd 1/5/06

VNUS

MEDICAL TECHNOLOGIES, INC.

January 3, 2006

Mark B. McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: **CMS-1502-FC**
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1502-FC Changes to the Medicare Physician Fee Schedule for CY 2007
CPT 36475 and 36476 Endovenous RF Ablation – Practice Expense

Dear Dr. McClellan:

On behalf of VNUS Medical Technologies, Inc. (VNUS) and physicians using our endovenous RF technology, we would like to address and resubmit comments on the Centers for Medicare and Medicaid Services (CMS) final rule with comment: Medicare Physician Fee Schedule (MPFS) Update for 2006. Concisely on VNUS's request for review of the inputs for both the practice expense- equipment and the work RVU's for new endovenous RF codes CPT 36475 & 36476 in 2005.

1. Practice Expense – Equipment - We appreciate CMS's acknowledgment of the need of the tilt table for Trendelenberg and reverse-Trendelenberg positioning in the endovenous ablation therapy procedure and for adding the equipment for the respective service period minutes for each code.

2.Practice Expense RVUs – Additional 15 minutes clinical labor- CMS did not recognize our request in the final ruling" ..the commenter's request for additional clinical labor is not timely because the RVU's for these new codes were published as interim in the CY2005 PFS final rule with comment at that time. " We apologize for this error, we thought our comment letter was received in the appropriate timeframe. Our comment letter was sent on September 29,2005 and was received by CMS on the September 30,2005 3:47 PM. I have attached the PDF showing the time stamp. We would like to resubmit our request for the CY 2007 to add 15 minutes of clinical labor to the PE database for CPT codes 36475 and 36476 .

The data from the NPRM labor cost input file includes 52 minutes of intra-therapy time for a vascular technologist. However, the vascular technologist has both pre- and post- therapy time of about 15 minutes for moving and setting up the ultrasound system between the vascular lab and procedure room. This "15 minutes" of time is not reflected in the NPRM labor file.

Therefore, CMS should increase the total technologist time to at least 67 minutes.
Such an increase is consistent with, but still lower than, the time and costs that CMS has recognized for conducting a duplex ultrasound diagnostic evaluation of the legs (e.g. CPT 93970) at 75 minutes of total therapy time.

Should you have any questions in the meantime, please contact me or Gail Daubert at 202.414.9241.
Thank you for your consideration.

Very truly yours,

Brian E. Farley

Brian Farley
President and CEO
VNUS Medical Technologies, Inc.

cc: Carolyn Mullen, CMS

2200 Zanker Road, Suite F, San Jose, CA 95131 • Telephone (408) 473-1100 • (888) 797-VEIN • FAX (408) 944-0292 • www.vnus.com

technologist. However, the vascular technologist has both pre- and post- therapy time of about 15 minutes for moving and setting up the ultrasound system between the vascular lab and procedure room. This "15 minutes" of time is not reflected in the NPRM labor file.

Therefore, **CMS should increase the total technologist time to at least 67 minutes**. Such an increase is consistent with, but still lower than, the time and costs that CMS has recognized for conducting a duplex ultrasound diagnostic evaluation of the legs (e.g. CPT 93970) at 75 minutes of total therapy time.

Equipment - Practice Expense

- The Equipment inputs for 36475 and 36476 fail to include at tilt table which is needed for the procedure. Accordingly, we recommend that CMS add $7,000 to the inputs for a tilt table.

CMS' proposed rule lists the following PE RVUs:

Code	Description	2005 Non-Facility PE RVUs	**CMS Proposed 2006** Non-Facility PE RVUs	2005 Facility PE RVUs	**CMS Proposed 2006** Facility PE RVUs
36475	RF, First vein with imaging guidance	51.39	**48.94 (-4.8%)**	2.53	**2.56**
36476	RF vein add-on w/ imaging	7.88	**7.59 (-3.7%)***	1.14	**1.16**
36478	Laser, First vein	46.77	**44.54 (-4.8%)**	2.53	**2.56**
36479	Laser, vein add-on	7.99	**7.69 (-3.7%)**	1.14	**1.16**

See 69 Fed. Reg. at 66,502 and 70 Fed. Reg. at 45,915.

*We wish to emphasize that the RF practice expense costs are significantly higher than the laser practice expense costs as evidenced by the difference in PE RVUs assigned to the primary procedures. Therefore, it is unclear why CMS assigned lower PE RVUs to CPT 36476 RF, vein add-on procedures in comparison to the laser, vein add-on procedure.

We recommend, at minimum, CMS **increase by 9% the PE RVUs for CPT 36476** and the facility PE RVUs for CPT 36475, consistent with the percentage of higher practice expenses associated with the primary procedure.

For CPT 36476, this means **CMS should, at minimum, –**

- **Increase the non-facility PE RVUs to 8.27; and**
- **Increase the facility PE RVUs to 1.21.**

For CPT 36475, this means **CMS should, at minimum, –**

- **Increase the facility PE RVUs to 2.79.**

II. Practice Expense Methodology – Overall Proposed Changes

We object to the proposed changes and decrease in PE RVU for the RF ablation procedures (CPT 36475 and 36476) for the following reasons.

75 Years of Caring 1930-2005

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

40

COPY

141 Northwest Point Blvd
Elk Grove Village, IL 60007-1098
Phone: 847/434-4000
Fax: 847/434-8000
E-mail: kidsdocs@aap.org
www.aap.org

December 28, 2005

rec'd 12/28/05
10:55 AM.

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule; **CMS-1502-FC**

Dear Dr McClellan:

The American Academy of Pediatrics (AAP) appreciates the opportunity to provide comments on the November 2nd Final Rule entitled Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006. Although very few pediatric services are included in the Medicare program, payment policies introduced in Medicare are frequently adopted by the Medicaid program and eventually by private payors. Therefore, the Academy offers these comments on the final rule to ensure that new policies appropriately accommodate the unique aspects of health care services delivered by primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

Relative Value Units for Non-Covered Services

The Academy strongly objects to CMS' failure to publish American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC)-recommended relative value units (RVUs) for "N" (noncovered) status codes, namely:

- Code 99173 (*screening test of visual acuity, quantitative, bilateral*) and
- Code 92551 (*screening test, pure tone, air only*)

Codes 99173 and 92551 have been through the RUC, where direct practice expense inputs were approved and recommended for inclusion in RBRVS. However, vision and hearing screening are Medicare non-covered services. CMS' refusal to publish RVUs for such pediatric services even though the codes have gone through the same validated valuation process as active Medicare codes distinctly disadvantages children, their providers, and children's preventive health services. CMS has a responsibility to publish RVUs for codes even when such services may not be covered under the Medicare program.

On page 66245 of the 2005 final rule (Vol. 69, No. 219, November 15, 2004), CMS noted, "because we have not yet established a consistent policy regarding the publication of RVUs for noncovered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for noncovered services." The AAP believes that CMS *already* has an established policy on noncovered services; it was developed when CMS published RVUs for the preventive medicine services codes (99381-99397). In fact, as more non-Medicare payors adopt RBRVS, it becomes increasingly important to include noncovered services and their RUC-recommended RVUs on the Medicare physician fee schedule. While CMS does note that it has included practice expense RVUs for a small number of noncovered services on the CMS Web site, such a supplement will not have the same effect as will the inclusion of the RVUs on the actual Medicare physician fee schedule.

Practice Expense For Immunization Administration Codes (90465-90474)

While the Academy applauds CMS for publishing the RUC-recommended RVUs for the immunization administration codes (90465-90474), we are concerned about the rank order anomalies introduced by the practice expense RVUs assigned to the oral/intranasal codes.

There are two subsets of immunization administration codes: 1) one for patients under age 8 (90465-90468); and 2) one with no reference made to patient age (90471-90474). Within each subset, there are two codes for injectable immunization administration and two codes for oral/intranasal immunization administration. While there is consistency across the two subsets for the injectable codes' practice expense RVUs (ie, 90465 versus 90471 and 90466 versus 90472), the oral/intranasal codes' practice expense RVUs do not demonstrate the same consistency (ie, 90467 versus 90473 and 90468 versus 90474). Given that all 8 of the immunization administration codes went through the identical RUC refinement process, it seems counterintuitive for the practice expense RVUs to create such rank order anomalies.

Therefore, we recommend the following:

1) CMS adjust the practice expense value for code 90467 by matching it to the practice expense value for code 90473 (0.19)
2) CMS adjust the practice expense value for code 90474 by matching it to the practice expense value for code 90468 (0.11)

Neonatal Continuing Intensive Care Services (99300)

The Academy applauds CMS for publishing the RUC-recommended work RVUs (2.40) for the new neonatal continuing intensive care service code (99300).

However, we would like to point out that there might have been an error made with regard to the malpractice RVUs for code 99300. The fee schedule indicates malpractice RVUs of 2.40, a value identical to the work RVUs for the code. Since such an elevated malpractice value creates a considerable rank order anomaly, it is our belief that the 2.40 malpractice RVUs for code 99300 may have been published in error. Based on the malpractice RVUs assigned to similar codes (ie, 99298-99299), the appropriate malpractice value should be approximately 0.15 RVUs.

Care Plan Oversight Services (99339 and 99340)

While the new care plan oversight codes (99339 and 99340) are included on the fee schedule, they are assigned to Status Indicator "B" (Bundled) and Status Indicator "I" (Not Valid For Medicare Purposes), respectively, and have no published values. CMS does not provide any explanation as to why it assigned these particular Status Indicators nor its decision to exclude the RUC-recommended RVUs for these codes.

During its April 2005 meeting, the RUC recommended work values of 1.25 (99339) and 1.80 (99340), where results of surveys were analyzed to ensure that the recommended work values accurately account for physician resources expended with the typical patient. It is our strong belief that the RUC-recommended RVUs should be published for codes 99339-99340, regardless of their assigned Status Indicators. In light of the fact that we are urging CMS to reevaluate its current policy with regard to the publishing RUC-recommended RVUs for noncovered services, CMS may consider designating codes 99339-99340 under Status Indicator "N" in order to allow for the RUC-recommended RVUs to be published.

Moderate (Conscious) Sedation (99143, 99144, 99145, 99148, 99149, and 99150)

The new moderate sedation codes (99143-99150) are included on the fee schedule as Status Indicator "C" (Carrier Priced), with no published RVUs. In its comments, CMS states that it is "uncertain whether the RUC assigned values are appropriate and has carrier priced these codes in order to gather information for utilization and proper pricing." While we appreciate CMS' reconsideration of paying for sedation services not previously covered and understand this is an interim position, we request that CMS consider the following arguments in revising its position.

These new CPT codes (99143-99150) were surveyed by several specialty societies in order to provide the RUC with data necessary to appropriately value the service. Codes were developed to simplify reporting these services into age-specific categories. The RUC-recommended values for these six codes were based on valid surveys and carefully vetted through the RUC process. We are confident in the accuracy of the values assigned. While CMS has assigned these codes to Status Indicator "C," the Academy believes that they should be listed with Status Indicator "A" (Active) and their RUC-recommended RVUs published.

Providing moderate sedation to patients undergoing certain outpatient procedures requires a certain level of provider skill and training and incurs medical legal liability, but is also associated with greater patient satisfaction, improved outcomes, and cost savings over similar procedures provided with anesthesia in an operating room.

Appendix G ("Summary of CPT Codes That Include Moderate Sedation") in the CPT manual was developed to identify services where sedation is an inherent part of the procedure. We firmly believe that any service performed that is *not* listed in Appendix G should be appropriately reimbursed when reported with a moderate sedation code. There is significant additional cognitive skill required and this is reflected in JCAHO mandates addressing specific credentialing criteria for individuals providing moderate sedation. The work involved in providing sedation is *not* included in the RVUs for any procedure not included in Appendix G

and the Academy believes that physicians should be adequately compensated for providing such services.

For these reasons, the Academy respectfully requests that CMS reconsider its decision to list the moderate sedation codes as carrier-priced. We urge CMS to publish the RUC-approved RVUs and assign these codes as Status Indicator "A" (Active) codes.

The Academy appreciates the opportunity to provide comments on the November 2nd final rule and looks forward to working with CMS to ensure that the physician fee schedule accurately reflects the work value of physician practice and pediatric care.

Sincerely,

Eileen M. Ouellette, M.D., J.D. FAAP

Eileen M. Ouellette, MD, JD, FAAP
President

EMO/ljw

41

American College of Surgeons

Washington Office: 1640 Wisconsin Avenue, NW • Washington, DC 20007 • 202/337-2701 • FAX 202/337-4271
e-mail: postmaster@facs.org ACS Web site: http://www.facs.org

January 3, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1502-FC
PO Box 8017
Baltimore, MD 21244–8017

Electronically submitted at
http://www.cms.hhs.gov/regulations/ecomments

RE: CMS-1502-FC Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B

Dear Dr. McClellan:

On behalf of the 70,000 Fellows of the American College of Surgeons, I am pleased to submit the following comments on the Final Rule published in the *Federal Register* on November 21, 2005. We will address the issues of practice expense (PE) relative value units (RVUs), professional liability insurance RVUs, multiple procedure reductions for diagnostic imaging, the oncology demonstration project, and the sustainable growth rate formula.

PE Proposals for CY 2006

In response to the comments submitted by the College and other medical specialty organizations, CMS has announced in the Final Rule significant revisions to its proposals on practice expense (PE) published in the Notice of Proposed Rule Making (NPRM) for the 2006 Medicare fee schedule. In particular, we are pleased that CMS has made the following decisions, which we comment on in

more detail below:

- Delay the use of new supplemental PE survey data, with the exception of the survey conducted by urology.
- Conduct a multi-specialty PE survey, with the involvement of the medical specialty societies.
- Institute a stakeholders process to exchange information and receive input from medical specialty organizations.
- Conduct a comprehensive review of the direct inputs developed by the Practice Expense Refinement Committee (PERC), which would involve the participation of the AMA/Specialty Society Relative Value Update Committee (RUC).

1. Supplemental PE Surveys

Section 303(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) requires CMS to use survey data submitted by a specialty group where at least 40 percent of the specialty's payments for Part B services were attributable to the administration of drugs in 2002. In accordance with this statute, CMS has accepted the practice expense per hour (PE/HR) data from the urology supplementary survey, which meets the 40 percent threshold, in the calculation of the PE RVUs for all the drug administration codes performed by urology. Other than the urology survey, CMS has delayed the implementation of the proposed PE/HR figures until a multi-specialty PE survey can be conducted. The College strongly supports this decision and wholeheartedly endorses CMS' plans to conduct a multi-specialty PE survey for indirect inputs for a uniform time period in consultation with medical specialties.

As we noted in our comments to the proposed rule, the dramatic changes in PE/HR that have been associated with recent supplemental surveys raise questions about the validity of the results. We are concerned that the use of these new survey data for a few specialties creates significant distortions in the relativity of practice expense payments across specialties. A multi-specialty survey has great potential to provide CMS accurate and updated information on the clinical resources required to perform a particular service. We urge CMS to take the opportunity to include questions in this survey that capture all resources necessary in providing services. We look forward to working with CMS and other medical specialty organizations to develop a strategy for fielding a multi-specialty indirect PE survey.

2. Revisions to the PE Methodology

In the Final Rule, CMS announces it will delay implementation of the revisions to the Practice Expense (PE) methodology proposed in the 2006 NPRM. This decision was made in response to the many concerns raised by medical specialty organizations, as well as the Medicare Payment Advisory Commission (MedPAC) that there was insufficient time and detail provided by CMS to properly understand the proposed methodology, to assess the impact of the proposed changes, or to offer meaningful comments. Additionally, CMS indicates in the Final Rule that it found an error in the program used to calculate indirect costs and, as a result, almost all of the PE RVUs published in the proposed Rule were incorrect. We appreciate CMS' responsiveness to requests from the College and other medical organizations to delay the implementation of the practice expense proposals in 2006 until enough data and information are provided to allow us to adequately review and assess the validity of the new methodology.

We also thank CMS for adopting the College's recommendation to conduct a stakeholders' process to address indirect PE methodological issues prior to finalization of any new methodology. CMS has indicated in the Final Rule that it would work with the medical community prior to the release of the next Proposed Rule to exchange thoughts on all of the issues raised, to answer any questions, and to provide additional data and corrected information. In the College's comments, we observed that CMS offered scant details of the proposed PE methodology in the August 9, 2005 *Federal Register*, thus making it difficult to gain a clear understanding of the proposal. We note that CMS has not provided any additional details in the Final Rule on the "bottom-up" methodology. Prior to the first stakeholders' meeting, it would be helpful for CMS to provide potential attendees of this meeting a detailed explanation of the methodology, with a "walk-through" using specific codes as examples, so that the medical community can provide the agency meaningful comments. We look forward to participating in this process and plan to provide CMS with constructive recommendations on valuing the PE component.

The College agrees with CMS that a review process is needed for the direct PE inputs to reflect changes in practice or new technology and to assure consistent application of clinical staff time standards and supply and equipment packages across all services. The PERC (formerly the Practice Expense Advisory Committee (PEAC))

has completed the immense and intricate task of refining the Clinical Practice Expert Panel (CPEP) data for all CPT codes. Exhaustive detail was given to this review and the PERC is to be commended for its work. However, since its creation, the review process the for direct inputs has continually evolved as the PERC developed standardized inputs for services similar in nature or in global period in an effort to provide uniformity and to make the refinement process more efficient. As a result, different "rules" and "standards" have been applied to different services, depending upon which stage of the process PERC was in when they were reviewed. We believe that a comprehensive review that compares codes within families and across different families is essential to ensure that all inputs are accurately reflected, relative to other services. This is particularly important for clinical staff time, as most of the PERC-created standards apply to this category of direct inputs. We are pleased to hear that CMS has asked the RUC to play a continuing a role in this further review and welcome the opportunity for the College to be involved in this process.

Professional Liability Insurance (PLI) RVUs

1. Five Percent Specialty Threshold

CMS announces that it is finalizing its proposal to exclude data for any specialty that performs less than five percent of a particular service or procedure from the professional liability (PLI) RVU calculation for that service or procedure. We appreciate CMS implementing this change, which we support and believe to be an improvement over the current PLI methodology. Excluding data for specialties that perform less than five percent of a service will remove data that could represent anomalous occurrences and should improve the accuracy and the stability of PLI RVUs. However, as we have stated in our comments to the proposed rule and in previous venues, the College advocates the use of the dominant specialty approach to determine which risk factor to apply to a CPT code, which would lead to more appropriate and acceptable PLI RVUs. The RUC, which has spent considerable time educating itself on the development of PLI RVUS and discussing potential methods to better derive these values, has also taken this position.

2. Specialty Crosswalk Issues

We support CMS' finalization of 1.0 as the risk factor for clinical psychologist, licensed clinical social worker, occupational therapist, psychologist, optician, optometrist, chiropractic and physical therapist. We were interested to hear that CMS' initial analysis of PLI premium data on these health professionals submitted by the

RUC's Health Care Professional Advisory Committee (HCPAC) suggests that the annual premiums paid by these groups are below the average amounts paid by the lowest premium cost physician specialties, which supports CMS' ruling.

We appreciate CMS' responsiveness to comments that the crosswalk for certified registered nurse anesthetists (CRNAs) should be from anesthesiology, rather than from the "all physicians" category (currently 3.04). As we stated in comments to the proposed rule, we do not believe CRNAs exceed the risk factors for anesthesiologists and are pleased that CMS has concurred with this view.

In the College's comments to the proposed rule, we recommended that CMS crosswalk hand surgery to orthopedic surgery (without spine) with the non-surgical and surgical risk factors of 8.06 and crosswalk colorectal surgery to general surgery with the non-surgical and surgical risk factors of 6.13. CMS disagrees in the Final Rule that these specialties should be crosswalked to other specialties because it used actual premium liability insurance data collected to develop the risk factors. CMS indicates that it only uses crosswalks for specialties for which no premium data are collected. Although we do not doubt CMS' collection of this premium data, we are stunned by the variance in the risk factors applied to colorectal surgery and general surgery and in those applied to hand surgery and orthopedic surgery (without spine). We request that CMS conduct an analysis of the data collected to determine whether it truly reflects the risk involved for these specific specialties. The College would be glad to work with CMS on this, as we believe that the current assignment of risk factors for these two specialties greatly underestimates the cost of PLI insurance.

We are also disappointed that CMS has maintained the crosswalk for obstetrics and gynecology that was published in the NPRM. We concur with the RUC PLI Workgroup's recommendation that the PLI risk factor for gynecologic oncologists, currently 5.63, should be crosswalked to surgical oncology, with a risk factor of 6.13. Although obstetrics and gynecology provide both surgical and non-surgical services, the cost of professional liability insurance is the same regardless of which type of service is provided. It does not make sense to base PLI RVUs for obstetrics and gynecology on premiums paid by physicians who offer only non-surgical gynecologic care. We strongly urge CMS to reconsider the recommendation of the RUC.

3. Cardiac Catheterization and Angioplasty Exception

CMS has finalized its proposal to add the following CPT codes to the list of cardiac catheterization and angioplasty codes that have been assigned surgical risk factors: 92975, 92980 to 92998, and 93617 to 93641. We agree that this exception properly recognizes that these procedures are more similar to surgical procedures than non-surgical procedures

4. Dominant Specialty for Low-Volume Codes

In the final rule, CMS again rejects the recommendation of the RUC PLI Workgroup to use the dominant specialty approach for services or procedures with fewer than 100 occurrences. Although we are encouraged that CMS has acknowledged that there may be instances where irregular data exist that would not be identified and removed by the five percent threshold method CMS is implementing, we still believe that the dominant specialty approach would reduce the variability of PLI RVUs from year to year for low-volume services, and so accomplish one of the goals of the resource-based relative value system. We urge CMS to reconsider the workgroup's recommendations for the 1,844 services that it has submitted to CMS.

Multiple Procedure Reductions for Diagnostic Imaging

As a revision to the NPRM, CMS is implementing a two-year phase-in of the changes in payments attributable to the multiple procedure reduction for diagnostic imaging. In the Final Rule, CMS is instituting the transition period to provide further opportunity for affected specialties to provide data and to comment on the efficiencies associated with different combinations of imaging services in the 11 impacted service families.

As we noted in our comments to the proposed rule, we strongly support CMS' position that redundancy of payment occurs when imaging procedures within the same code family are performed during the same session on contiguous body areas. Adjusting Medicare payments to reimburse fully for the technical component (TC) of the highest priced procedure and pay 50 percent of the TC for each additional procedure corrects for the efficiencies achieved when performing multiple procedures. Technologists use many of the same supplies and equipment for a second procedure as they do for the first procedure within these families. Similarly, all clinical staff activities are not repeated for additional procedures, such as greeting the patient and providing gowning. This reduction has been applied to surgery for 30 years and we see

no rationale explaining why it should not be imposed on other procedures. We encourage CMS to move forward with the imaging proposal and identify for next year's proposed rule other imaging and diagnostic services where similar efficiencies are readily apparent.

Oncology Demonstration Project

CMS announces in the Final Rule that it will continue the chemotherapy demonstration project for an additional year, but will reconfigure the project and alter the reimbursement for the services provided. We are disappointed by CMS' decision to extend the oncology demonstration project for reasons we have stated in our comments to the proposed rule. Our concerns with the demonstration were heightened when we reviewed the preliminary assessment provided by the Office of Inspector General (OIG), which identifies several issues with the reliability and usefulness of the data and the appropriateness of the payments.

Certainly the revisions to the demonstration project that CMS is implementing offer a vast improvement over the original version. We are pleased that CMS has responded, in part, to the College's concerns that the current project does not focus on evidence-based medicine by indicating that it will gather more specific information relevant to the quality of care for cancer patients, including the treatments provided and the adherence to clinical guidelines. We are also glad to note that CMS has reduced the payment for the collection of information to a more appropriate level. The amount reimbursed in 2005 of $130.00 per encounter is more than the reimbursement for a level five office visit for an established patient, which typically requires 55 minutes of physician time. We judge this to be an extreme overpayment, particularly since the OIG's initial observation is that the three questions posed to patients were typically asked by nursing staff and were already part of the routine care of chemotherapy patients.

Our position is that the demonstration project, even revamped, offers questionable benefits to cancer patients; however, since CMS has decided to extend the project through 2006, the College finds it problematic that CMS continues to limit participation to oncologists and hematologists when many types of physicians treat cancer patients. For example, surgeons such as urologists, who treat prostrate and other cancers, are excluded from the program. This makes no practical sense and raises the question as to whether the project is primarily a mechanism for income supplementation for the affected specialties, rather than a legitimate endeavor to improve the quality of cancer care. We urge CMS to take a hard look at the

demonstration project, as it gathers additional data, to ascertain the extent to which the program has offered any benefit to cancer patients.

Interim Relative Value Units – Transplant Backbench Work

In February 2004, the CPT Editorial Panel approved a comprehensive package of coding changes for backbench work on organs undergoing transplantation. The package contained two types of codes: standard backbench work that is done on all transplantations and reconstruction work done for selective transplantations. As previous Medicare regulations and guidance did not specifically address whether these services should be treated as a Part B services paid under the MFS, or reimbursed under Part A, the American Society of Transplant Surgeons (ASTS) presented its reasoning to CMS that backbench work should be considered part of organ acquisition costs and reimbursable under Part A. In the Final Rule, CMS disagrees with these recommendations and states that it considers all backbench work, including standard backbench work, to be payable under Part B.

The College differs with CMS's interpretation of the handling of standard backbench work on organs harvested for transplantation. The standard backbench work, which is always necessary to prepare a graft for transplantation, may be done before a recipient has been identified. In addition, there is a special problem with private insurance: if a recipient has been identified, the work may be done at a site remote from the patient so it is possible the surgical team does not have contractual arrangements with the recipient's insurer. The work is also extremely variable in that graft preparation may involve "splitting" grafts and then transplanting in two or more recipients at more than one location, or sending a prepared graft to a different site if the original recipient dies. For these reasons and others, the College believes that the standard backbench work, which has always been considered part of organ acquisition costs, should be reimbursed through Part A.

The reconstruction work, which is not typically performed, involves specific alterations (typically anastomoses) to the organ to make it suitable for transplantation into a specific recipient. The eight new codes representing reconstructive backbench work for organ transplants allow the surgeon who performs the service, and who is generally not part of the recipient transplant team, to properly report the procedure. Therefore, we agree with CMS that these codes should not be considered part of the hospital's organ acquisition costs but should be paid under the physician fee schedule.

Sustainable Growth Rate (SGR)

At the drafting of these comments, the College is hopeful that Congress will be successful in passing legislation to halt the scheduled –4.4 percent Medicare update announced in the proposed rule. Although this will help the immediate problem physicians would otherwise face in 2006, it does nothing for the long-term viability of physician payments. The College regrets that CMS has, once again, failed to take any steps to address the problems of the SGR formula. As we have stated in response to the proposed rule, and in many other communications, we believe that CMS has some discretion in the determination of the update factor and recommend the following changes:

1) Exclude drugs from the definition of "physician services" as it relates to the calculation of the SGR

We believe that CMS' inclusion of the growth of drug prices in the allowed and actual expenditures for physician services contradicts the Medicare statue. Furthermore, we disagree with CMS's assumption that physicians are able to control utilization, and therefore spending, on drugs. Rising drug costs are due primarily to the explosion of expensive new drugs entering the market and direct-to-consumer advertising, over which physicians have little control.

2) Adjust the physician spending target to reflect technological improvements

Although Congress has attempted to build allowances for technological improvements into other payment systems, CMS does not adjust the physician spending target for these improvements in the fee schedule. Instead, expenditure increases stemming from technological advances simply go into the pool with all other physician/practitioner expenditures, thereby increasing the possibility that the target will be exceeded and that payments will be cut as a result.

3) Adjust the physician spending target to account for shifts in site of service

The movement of surgical and other procedures from the outpatient hospital setting to the physician office setting, where the assigned PE RVUs are significantly higher, results in an increase in actual expenditures compared to the allowed spending growth under the target. We recommend that CMS recognize this movement to the office setting and make appropriate adjustments to the target so that all physicians

are not penalized by a change that is produced by the resource-based payment methodology.

Ultimately, we need a system that enables reimbursements to keep pace with physicians' costs. The SGR system has to be reformed, with future payments linked to a reasonable measure of practice cost inflation such as the Medicare Economic Index. We reiterate our support the Medicare Payment Advisory Commission's recommendation to replace the SGR with an annual update system like those of other provider groups so that payment rates will better reflect actual increases in practice costs.

Lastly, we note that CMS dedicates a significant portion of its response to comments relating to the SGR in the Final Rule discussing the need for Medicare to encourage and reward efficiency and high quality care, and not simply pay for more services. With respect to pay for performance or value-based purchasing, the College is optimistic that such a program, if properly designed, holds great promise for truly imposing some rationality on the physician payment system. We agree that it is time to shift the focus away from the "price" Medicare pays for a service and toward the "effectiveness" of the care that patients receive.

Since the College's founding over 90 years ago, it has demonstrated its commitment to ensuring high-quality surgical care for patients. This commitment to excellence in surgery is evident in the professional standards to which our Fellows are held and in the wide range of educational services that the College offers to ensure that they maintain their skills and learn about advances in technology and practice. We set standards for trauma care, we approve hospital cancer programs, and we have developed standards for bariatric surgery programs. With respect to promoting processes and data collection to improve surgical outcomes, the College has partnered with CMS and the Centers for Disease Control and Prevention in the Surgical Care Improvement Project (SCIP), and first with the Department of Veterans Affairs and now with hospitals and health plans in the National Surgical Quality Improvement Project (NSQIP). The College believes strongly that, if value-based purchasing in Medicare is to be successful, physician measures must be based on physician-led efforts such as these public-private partnerships, which have been shown to improve outcomes for patients and lower healthcare costs.

It is important to note that the diversity of physician services and the settings in which they occur must be taken into account in the design of a value-based purchasing program. Surgeon-led quality improvement initiatives, for example, tend to focus on the

entire episode of care and the system in which patient care is provided. Surgery is a team effort, and our quality and safety efforts incorporate all elements of that team. This is a very different approach from the more narrowly drawn process measures that have been developed for other service types. Surgical care also lends itself more readily to risk-adjusted outcomes measurement than many primary care services for which success relies more heavily on patient compliance factors beyond the physician's control. Finally, the potential for cost savings through improvements in the quality of surgical care can be tremendous. For example, it has been estimated that taking the necessary steps to prevent post-operative pneumonia can save $22,000 to $28,000 per patient admission for cases in which complications occur. However, for Medicare these savings are achieved outside the Part B physician payment system, a complex issue that needs to be addressed if payment incentives are to truly be aligned to favor cost effectiveness and quality improvement.

Nevertheless, the College stands ready to work with Congress and with CMS to ensure that any value-based purchasing reforms are structured in such a way to properly reward high-quality care and to promote advances that will improve the quality of surgical care in the future.

Conclusion

The College has commented on the issues of PE RVUs, professional liability insurance, multiple procedure reductions for diagnostic imaging, the oncology demonstration project, and the SGR. We appreciate the opportunity to provide input on these important issues and we look forward to working with CMS on them in the coming year.

Sincerely,

Thomas R. Russell, MD, FACS
Executive Director

wo:TRR:CB//jh//cc

42

ASTRO
AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

January 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

RE: CMS-1502-FC; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Supplemental Pricing Information for Supplies and Equipment

Dear Dr. McClellan:

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to provide comments on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 announced in the *Federal Register* on November 21, 2005. Our comments in this letter focus solely on the repricing of clinical practice expense inputs – Supply and Equipment Items Needing Specialty Input. This letter is in addition to our primary comment letter, dated January 3, 2006, responding to other Medicare Fee Schedule issues.

Supply and Equipment Items Needing Specialty Input (70 Fed. Reg., 70140)

We are responding to your request that specialty groups provide the necessary pricing information, including appropriate documentation, for several radiation oncology items. More specifically, we have reviewed Table 14: Supply Items Needing Specialty Input for Pricing and Table 15: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions. From Table 14, there was one supply item we identified relating to radiation oncology, as well as two equipment items listed in Table 15 that need price information. We are providing documentation per this request, including a list of price quotes for each of the items (see Attachments 1 through 4). **We *strongly request that CMS maintain these radiation oncology items, although proposed for deletion, as they remain necessary items for cancer treatment. It is imperative that radiation oncologists receive reimbursement for these items in order to maintain essential treatments for their patients.***

Due to office schedules during the holidays, we experienced difficulty obtaining pricing information for some items on which we wish to comment. CMS then granted us a short extension for submitting

[1] *ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.*

12500 Fair Lakes Circle
Suite 375
Fairfax, VA 22033
p 800.962.7876
703.502.1550
f 703.502.7852

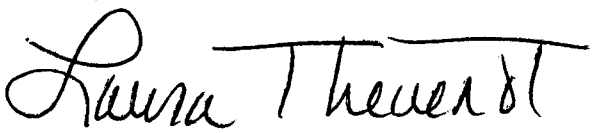
pricing information. We are now submitting that pricing information to you. We thank you for your patience in this matter.

The following items are what ASTRO would like CMS to consider not deleting from the CMS supply and equipment database:

a) Sealant spray; CMS Supply Code SL119 [*Federal Register - Table 14* did not list a price for 2005], associated with CPT® code 77333; *Treatment devices, design and construction; intermediate(multiple blocks, stents, bite blocks, special bolus*;
b) Hyperthermia system, ultrasound, intracavitary; CMS Equipment Code ER036 [*Federal Register Table 15* – 2005 price was $250,000], associated with CPT® code 77620; *Hyperthermia generated by intracavitary probe(s)*; and
c) Orthovoltage radiotherapy system; CMS Equipment Code ER045, [*Federal Register Table 15* – 2005 price $140,000]; associated with CPT® code 77401; *Radiation treatment delivery, superficial and/or orthovoltage*

The American Society for Therapeutic Radiology and Oncology appreciates the opportunity to offer these comments and looks forward to working with CMS to address these important issues. If you require further information, please contact Debra Lansey, MPA, Assistant Director of the Department of Health Policy, at (703) 502-1550.

Respectfully,



Laura Thevenot
Chief Executive Officer

cc: Herb Kuhn
Kenneth Simon, M.D.
Edith Hambrick, M.D.
Marc Hartstein
Carolyn Mullen
Pam West
Trisha Crishock, MSW

Enclosed:

Attachment 1: Table of ASTRO's Pricing for Supplies and Equipment Needing Specialty Input
Attachment 2: Sealant Spray – CMS Supply Code SL119
Attachment 3: Hyperthermia system, ultrasound, intracavitary – CMS Equipment Code ER036
Attachment 4: Orthovoltage radiotherapy system – CMS Equipment Code ER045

Attachment 1: Table of ASTRO's Pricing for Supplies and Equipment Needing Specialty Input

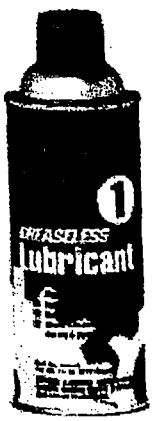
1	SL119	Sealant spray	No price	Radiation oncology	77333	Source A	$9.75

1	ER036	Hyperthermia system, ultrasound, intracavitary	$250,000	Radiation oncology	77620	Source A	$282,575
2	ER045	Orthovoltage radiotherapy system	$140,000	Radiation oncology	77401	Source A	$251,450

ATTACHMENT 2: SEALANT SPRAY

PILOT SUPPLIES
New Products
Closeouts
Aircraft Manuals
Aircraft Supplies
Apparel
Avionics
Books
Charts
Checklists
ELT's/TPAS/PLB's
FAA Test Guides
Flashlights
Flight Bags
Flight Computers
Flight Guides
Flight Jackets
Flight Simulators
GPS Systems
Gifts for Pilots
Hand Mic's
Headsets
Health/Safety
Helicopter Section
IFR Training
Intercoms
Jeppesen Section
Kneeboards
Log Books
Oxygen Systems
Pilot Supplies
Plotters
Pro Pilot Section
Scanners
Seat Cushions
Software
Sport Pilot
Sunglasses
Training Kits
Transceivers
Videos/DVD's
Watches

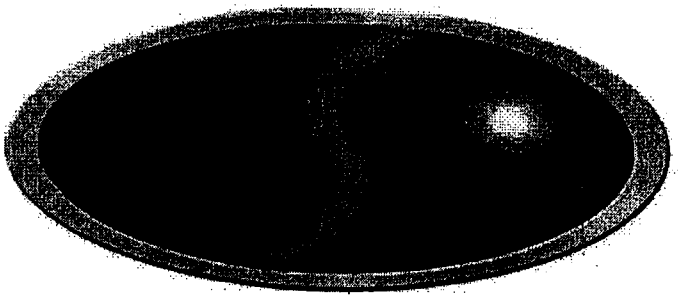
LPS



LPS1 Greaseless Lubricant
Our Price: $9.75 ~~**MSRP $11.18**~~
Add to Cart

Features

- Dries fast and resists oil, dust and dirt build-up
- Provides a dry, thin lubricating film
- Fast acting penetration
- Displaces moisture
- Loosens rusted or frozen parts
- Provides short term light corrosion resistant barrier
- Resist film build-up
- Nonflammable propellant
- Ideal for delicate mechanisms
- Safe on paint and most plastics
- Used worldwide in aviation
- Protects tools from rust
- Inverta Spray Valve



This Quotation for a

BSD-500 Hyperthermia System

915 MHz Microwave

has been prepared exclusively for:

ASTRO
12500 Fair Lakes Circle
Fairfax, VA 22033

Attention: Omari Keeles

By:

BSD Medical Corporation
"The Hyperthermia Company"
2188 West 2200 South
Salt Lake City, Utah 84119-1326 USA

Telephone: 801-972-5555
Facsimile: 801-972-5930
Email: sales@bsdmc.com

Submitted this date: December 8, 2005

Quotation Number: 020706-2729

This Quotation is valid until: February 7, 2006

BSD MEDICAL CORPORATION is pleased to submit this quotation to:

ASTRO
12500 Fair Lakes Circle
Fairfax, VA 22033

Attention: Omari Keeles

BSD MEDICAL CORPORATION offers to sell the product(s) described herein at the prices and terms stated in the *Standard Terms and Conditions of Sale*.

Quantity	*Product Description*	*Pricing*	
One	**BSD-500 Hyperthermia System** 915 MHz Configuration	List	$282,575.00

Food and Drug Administration Status of the Device
The BSD-500 Mobile Hyperthermia System has Premarket Approval from the U.S. Food and Drug Administration. The BSD-500 Mobile Hyperthermia System is to be used only by qualified operators upon the prescription and under the supervision of a physician who is experienced in clinical hyperthermia.

The Special Price listed on page 2 of this quotation includes the following System Components and Accessories. Optional equipment items and pricing are attached. The price for optional equipment items has not been included in the Special Price.

If the Customer agrees to the terms of this quotation, they should: read and agree to the *Standard Terms and Conditions of Sale* and any addendum's to these conditions as listed in this quotation.

The BSD-500 Hyperthermia System Equipment configurations includes:

MOBILE OPERATOR CONTROL CONSOLE AND SIDE CONSOLE

Component	*Specifications*
Computer System	Pentium III 1GHz/133MHz FCPGA CPU 3.5 Inch 1.44 MB Diskette Drive 40 G Byte Hard Disk Drive CD540E/B: Teac, ATAPI, 40X, CD ROM Drive 512 MB Low Profile DIMM Memory Two Data Control and Acquisition PCI Cards: Analog Input/Output, 16 Bit Resolution, Digital I/O
Operating System Software	Pre-Treatment Planning (For Interstitial) Hyperthermia Treatment Procedures Temperature and Thermal Dose Monitoring Procedures Treatment Recall User and Diagnostic Programs
Control Panel	AC ON/Off Switch for immediate emergency shut down Enhanced 105 key, Silent Tactile Keyboard
Color Monitor	Flat Panel Color Active Matrix 1024 x 768 15-inch diagonal, Non-Glare screen Touch Screen Controls Operator Interface
Printer	USB printer
Temperature Probe Thermometry and Interface	Sixteen (16) Inherently Stable Thermistor Type Temperature Probe (Model TP110) with non-metallic leads, non-perturbing to microwave fields. Probes display to an accuracy of ± 0.1° C. Thermometry Interface Connection Panel One (1) Probe Simulator
Probe Calibration Thermal Well	Thermal Well for single point calibration and verification typically at 42°C. Internal NBS standard sensor controller. Separate Reference Probe for secondary Thermal Well temperature verification.
Integral Water Bolus System	Operating Modes: Fill, Drain, Circulate, Heat, and Cooling. Temperature Range: 25°C to 40°C Heater: 300 Watts Cooler: Room Air heat exchanger Reservoir Volume: 1.8 liters

915 MHz MICROWAVE

Component	*Specifications*
Microwave Generator	Output Frequency: 915 MHz Eight (8) Independent Channels; can be switched to a single output (400 W) Forward and Reflected power of all eight (8) channels (50 W) are monitored by the computer Phase Control
Applicator Set	Two (2) Model MA-100 side loaded applicator (Aperture size: 10 by 13 cm.) Two (2) Model MA-120 large side loaded applicator (Aperture size: 18 by 24 cm.) Two (2) Model MA-151 mini dual ridge applicator (Aperture size: 6.4 cm. diameter)
Microwave Interstitial	Forty-Eight (48) Model MA-251NT interstitial applicators which radiate heat to the tip of the antenna and are insertable into Sixteen (16) gauge closed tip or radiation implant catheters Eight (8) Channels of independent control of up to Eight groups of interstitial applicators, Twenty-Four (24) applicator maximum capability

THERMAL MAPPING SOFTWARE SYSTEM

Component	*Specifications*
Thermal Mapping Software	The Thermal Mapping System is a software system to add a comprehensive set of manual sensor pull-back mapping for temperature data storage, thermal dose calculation, display, and printout capabilities. Thermal mapping is an advanced thermometry probe movement tracking system that periodically enables operator to manually shift temperature probes to multiple locations within implanted catheters during treatment and display and record data at these points. Temperatures are automatically recorded during this process to provide temperature scans along catheter lengths. Up To Seven (7) Model TP110 Temperature Probes Can Be Mapped Scan Length: 0 cm To 30 cm Scan Points: 0.5 cm To 30 cm Apart Time Interval Between Scans: Manually initiated Thermal Dose Calculated For Each Dwell Point Temperature Scan Plots Can Be Displayed and/or Printed

ACCESSORIES

Component	*Specifications*
Spare Bolus Diaphragms	Two (2) diaphragms for Model MA-100 Two (2) diaphragms for Model MA-151 Two (2) diaphragms for Model MA-120
Diskettes	Ten (10), 3.5", 96 high-density w/storage case
Printer Paper	One (1) box inkjet paper
Manual Kit	BSD-500 Operator Manual Set and OEM Manual Set
Phantom Packs	Six (6) muscle equivalent phantom packs (delivered at installation)

MA-252 Microwave Interstitial (Esophageal) Applicator	Usable for esophageal treatments when inserted in a six (6) lumen applicator tube available from Alpha Omega (identified as the 60 cm Nasogastric Applicator -- NOT INCLUDED.) Insertion length of 57 cm Made of semi-rigid coaxial cable (.84 mm diameter) 1.14 mm tip diameter 50% heating patter length approximately 6-8 cm
Superficial Interstitial Bolus w/MA-250 Interstitial Applicators	Silicone rubber conformal bolus 10 cm X 20 cm Water flow provided through two (2) quick disconnect hose fittings Eight (8) integral applicator support tracks and includes Velcro strap for attachment to patient Includes eight (8) MA-250 Interstitial Applicators Flexible coaxial cable connects to an applicator having a 4.5 cm long active heating length, heating pattern extends to the tip of the applicator Also insertable into sixteen (16) gauge catheters Does NOT include integral thermometry Additional MA-250 Applicators are available at $308.00 each
Hazard Meter	One (1) electromagnetic radiation hazard meter (battery operated)

STANDARD TERMS AND CONDITIONS OF SALE

All BSD Medical Corporation products and services are furnished on the terms and conditions stated herein and in the applicable BSD Medical quotation, notwithstanding any terms or conditions on the Customer's purchase order. BSD Medical's performance of any contract is expressly made conditional on the Customer's agreement to BSD Medical's Terms and Conditions of Sale unless otherwise agreed to, in writing, by BSD Medical. In the absence of such agreement, commencement of performance and/or delivery will be for the Customer's convenience only and will not be deemed or construed to be acceptance of the Customer's terms and conditions. If a contract is not earlier formed by mutual agreement in writing, acceptance of the product or service shall be deemed as acceptance of BSD Medical's Terms and Conditions. The Customer shall cooperate fully with BSD Medical to execute such documents and accomplish such filings and/or recordings thereof as BSD Medical may deem necessary for the protection of its interests in the product furnished to the Customer.

Item One: Quotations and Prices

BSD Medical's prices, quotations and contracts are subject to the following unless otherwise stated in writing:

(a) All quotations are firm and expire sixty (60) days from the date thereof and constitute offers.

(b) BSD Medical's performance is conditioned upon and subject to BSD Medical's approval of Customer's credit. Customer agrees to provide all information reasonably requested by BSD Medical to carry out credit approval.

(c) All prices quoted are for the products and services only and are exclusive of all transportation, crating, handling, special packing, insurance costs, and any taxes (including, without limitation, any sales taxes, license fees, customs fees or duties, and other related charges).

(d) Any and all taxes levied on or with respect to the products after completion of manufacture or scheduled delivery date shall be paid by the Customer.

(e) Clerical and typographical errors are subject to correction.

(f) Published weights and/or dimensions are approximate only.

(g) Prices and delivery dates quoted are subject to receipt of prior orders. Prices are valid only for the delivery and payment schedule specified.

(h) A handling charge of $35.00 will be applied to all orders under $200.00.

Item Two: Terms of Payment

Fifty percent (50%) advanced payment with order and fifty percent (50%) due upon notification of shipment. BSD Medical must approve any alternative payment schedule and resulting price change, in writing. All PAST DUE BALANCES shall be subject to a finance charge at the rate of 1.75% per month (21% per year). Partial shipments will be invoiced as made and payments therefore are subject to the above terms. Any applicable sales taxes will be added to invoice, unless proper tax exemption certificates and/or forms are provided to BSD Medical. BSD Medical may cancel or delay delivery of products or services in the event of an arrearage in Customer's account with BSD Medical. BSD Medical shall retain a purchase money security interest in all products and the proceeds thereof until Customer has made payment in full in accordance with the terms hereof.

Item Three: Transportation and Risk of Loss

Unless otherwise expressly agreed by BSD Medical in writing, all sales and shipments are F.O.B. Factory Salt Lake City, with all transportation and insurance at the expense of Customer. Transportation to Customer's site will be by best available carrier, unless some other means of transportation is agreed upon and approved in writing by BSD Medical. Unless specifically requested otherwise, in writing, BSD Medical may, at Customer's expense, insure to full value of the products shipped or declare full value to the Transportation Company at the time of shipment. Risk of loss and/or damage shall pass from BSD Medical to the Customer upon delivery of the products by BSD Medical to the Transportation Company.

Item Four: Specifications

Products supplied and installed by BSD Medical will be in accordance with the written specifications, as provided by BSD Medical to Customer and referred to in BSD Medical's applicable quotation. Minor deviations from such specifications shall not be made the basis of any claim against BSD Medical. BSD Medical shall not be responsible for performance figures given in any source, including but not limited, to advertisements and catalogs. Specifications are subject to change without prior notice. In the interest of conservation of scarce materials, and of efficient utilization of high value parts, products may contain remanufactured parts. Such parts are subject to the same high standards of quality control applied to other parts and are covered by the standard warranty as applicable.

Item Five: Performance

Dates specified for delivery or other performances are best current estimates only and failure to perform on or by such dates shall not subject BSD Medical to any liability. BSD Medical shall not be liable in any way because of delay in performance hereunder which is due to acceptance of prior orders, technical difficulties, unforeseen circumstances, or to causes beyond its control, including, without limitation, strike, lockout, riot, war, fire, act of God, accident, failure or breakdown of components necessary for order completion, subcontractor, supplier or Customer caused delay's, inability to obtain or substantial rises in the price of labor, materials or manufacturing facilities, curtailment of or failure to obtain sufficient electrical or other energy supplies, or compliance with any law, regulation or order, whether valid or invalid. Provided any such delay is neither material nor indefinite, BSD Medical's performance shall be deemed suspended during and extended for such time as it is so delayed, and thereafter Customer shall accept performance hereunder. As used herein,

"performance" shall include, without limitation, fabrication, shipment, delivery, assembly, installation, testing, and warranty repair or replacement, as applicable.

Item Six: Storage of Shipments

If, because of delays in completion of Customer facilities, or for any other cause, Customer requests a delay in the scheduled shipment date, Customer hereby authorizes BSD Medical to ship the product to a storage facility, upon completion of its manufacture. Customer shall be responsible for all storage-related charges, including insurance. Customer shall pay any payment increments due upon shipment at the time of such shipment to the storage facility. Title and risk of loss and/or damage shall pass from BSD Medical to Customer on delivery of equipment to the Transportation Company, at BSD Medical's factory. All storage related charges must be paid prior to the actual shipment of products to the Customer's facility.

Item Seven: Installation

Installation is included with the price quoted, BSD Medical shall notify Customer prior to the scheduled shipment of the product to coordinate installation details. A BSD Medical representative will perform installation. BSD Medical will assemble and test the product. Operation of equipment as necessary for completion of installation or acceptance tests is subject to provision by Customer of adequate shielding and other site preparations required for the safety and protection of BSD Medical personnel and equipment. Upon completion of the installations, BSD Medical representatives will demonstrate proper machine operation by performing BSD Medical's Acceptance Test Procedure for the product shipped. Customer will be responsible for having the building, utilities, lighting, ventilation, air conditioning, mounting facilities, all necessary shielding, and access to the room completed, per the room requirement specifications as provided by BSD Medical, and be ready for the installation of the product on or before the estimated delivery date. Customer shall provide a representative who will be available at all times during the installation and be capable of assisting the installation where necessary. If the representative from the Customer is not available when required by BSD Medical, the installation shall be discontinued and the Customer shall be charged for any additional costs incurred. BSD Medical will, if requested and as a convenience to the Customer, assist the Customer in locating a local licensed contractor. In cases where BSD Medical supervises such work, BSD Medical shall act solely as Customer's agent and shall have no responsibility or liability of any kind. Should completion of installation be delayed due to union action or influence, Customer shall, as soon as possible, make such arrangements as may be necessary for the work to be carried out at the Customer's expense by the Customer under the engineering supervision of BSD Medical.

Item Eight: Local Requirements

Customer shall be responsible for obtaining all permits, licenses, and requirements of any kind whatsoever relating to state and local codes, registration, regulations and ordinances. BSD Medical makes no warranty of any kind regarding compliance by the Products with such requirements.

Item Nine: Acceptance

All Products furnished by BSD Medical shall be deemed accepted by Customer upon completion, by BSD Medical, of its applicable acceptance tests or execution of BSD Medical's acceptance form by Customer. Notwithstanding the foregoing, use of any Product by Customer, its agents, employees or licensees, for any purpose after delivery thereof, without express written approval of BSD Medical, shall constitute acceptance of the Product by the Customer. Prior to acceptance, BSD Medical may repair, or at its option, replace defective or nonconforming parts after receipt of notice of defect or nonconformity. After acceptance, Customer's remedies shall be as provided in the Warranty paragraph herein.

Item Ten: Patents

BSD Medical will hold Customer harmless with respect to any claim that the design or manufacture of any item in BSD Medical's commercial line of Products constitutes an infringement of any patents or other industrial property rights of the United States or Canada. BSD Medical will pay all damages and costs either awarded in a suit or paid in BSD Medical's sole discretion, by way of settlement, which is based on such claim of infringement, provided BSD Medical is notified promptly in writing of such claim if infringement and is given full authority information and assistance in settling or defending such claim. BSD Medical will, in its sole discretion and at its own expense, either procure for Customer the right to continue using said Product, or replace it and refund an equitable portion of the selling price and transportation costs. This shall constitute BSD Medical's entire liability for any claim based upon or related to any alleged infringements of any patent or other industrial property rights.

Item Eleven: Warranty

Unless otherwise agreed to in writing, BSD Medical warrants that the Products it sells will be free from defects in material and workmanship for a period of one (1) year from the date of shipment. Repair, or at BSD Medical's option, replacement of defective parts shall be the sole and exclusive remedy under warranty. If in BSD Medical's opinion such repair or replacement is not feasible, or if such remedy fails in its essential purpose, BSD Medical may elect to negotiate with the Customer a refund of an equitable portion of any sum paid by the Customer for the product. All warranty repair or replacement of parts shall be limited to equipment malfunctions which are, as determined by BSD Medical, due and traceable defects in original material or workmanship. All obligations of BSD Medical shall cease in the event of abuse, accident, alteration, misuse or neglect of the Product. In-warranty repair or replacement parts are warranted only for the unexpired portion of the original warranty period. THIS WARRANTY IS EXPRESSLY IN LIEU OF AND EXCLUDES ALL OTHER EXPRESSED OR IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE, USE OR APPLICATION, UNLESS OTHER WARRANTIES ARE EXPRESSLY AGREED TO IN WRITING BY BSD MEDICAL.

Item Twelve: Indemnity

If it is determined in accordance with applicable law that any fault or neglect of BSD Medical, its employees or agents, substantially contributes to damage or injury to third parties, BSD Medical shall be responsible in such proportion as reflects its relative fault thereof, but shall have no other or further responsibility with respect to any such damage or injury. Customer shall be responsible for, and shall hold BSD Medical harmless from, all other liability for damages arising out of or related in any way to any Product or service furnished to Customer by BSD Medical. Notwithstanding the foregoing, and notwithstanding any fault or neglect attributable to BSD Medical, BSD Medical shall have no responsibility whatsoever for,

and Customer shall hold BSD Medical harmless from, any and all damage or injury which (1) may result during use, operation or service of any product of BSD Medical by other than BSD Medical personnel prior to completion of applicable acceptance tests by BSD Medical, or (2) may result from or relate to any use, operation or service of any product of BSD Medical contrary to any written warning or instruction given by BSD Medical to Customer with respect to such Product.

Item Thirteen: Damages and Liability

IN NO EVENT SHALL BSD MEDICAL BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL, SPECIAL OR RESULTING LOSS OR DAMAGE. BSD MEDICAL'S AGGREGATE LIABILITY TO CUSTOMER SHALL BE LIMITED TO PAYMENT ACTUALLY RECEIVED BY BSD MEDICAL FOR THE SPECIFIC UNIT OR PRODUCT OR SERVICE FURNISHED OR TO BE FURNISHED RESULTING IN THE LOSS OR DAMAGE CLAIMED.

Item Fourteen: Computer Program License

Computer programs, which may be provided with the Products, remain the property of BSD Medical or BSD Medical's licensees. BSD Medical hereby grants the Customer a nonexclusive royalty-free right to use such programs only in machine-readable form and only in combination with the Products with which such programs are provided. Customer agrees not to provide any program, or any portion thereof to any third party. This license shall terminate when Customer discontinues use of the programs or the Products with which such programs are provided, and upon such termination, all program materials shall be returned to BSD Medical by the Customer.

Item Fifteen: Confidential and Proprietary Information

All drawings, designs, specifications, manuals and programs furnished to the Customer by BSD Medical shall remain CONFIDENTIAL and PROPRIETARY property of BSD Medical. All such information except as may be found in the public domain, shall be held in confidence by the Customer and shall not be disclosed by the Customer to any third parties. Copyright in all materials made available by BSD Medical shall remain with BSD Medical at all times.

Item Sixteen: Cancellations and Assignments

No order accepted by BSD Medical may be canceled or assigned by the party placing the order except by prior written consent of BSD Medical. Any attempt to assign or cancel without such approval shall be void.

Item Seventeen: Disputes and Governing Law

All disputes under contract concerning Products not otherwise resolved between BSD Medical and Customer shall be resolved in a court of competent jurisdiction, in Salt Lake County, State of Utah, and in no other place, provided that, in BSD Medical's sole discretion, such action may be heard in some other place designated by BSD Medical (if necessary to acquire jurisdiction over third persons), so that the dispute can be resolved in one action. Customer hereby consents to the jurisdiction of such court or courts and agrees to appear in any such action upon written notice thereof. No action, regardless of form, arising out of, or in any way connected with, any Product or service furnished, or to be furnished, may be brought by Customer more than one (1) year after the cause of action has occurred.

Item Eighteen: Entire Agreement

This agreement contains the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior oral understandings, representations and warranties. If any part of the terms and conditions stated herein are held void or unenforceable, such part will be treated as severable, leaving valid the remainder of the terms and conditions.

Addendum to:

STANDARD TERMS AND CONDITIONS OF SALE

TERMS OF PAYMENT:

Fifty percent (50%) of the listed System Price (including any optional equipment) required as down payment with order.

Fifty percent (50%) of the listed System Price (including any optional equipment) is due upon delivery of equipment. All charges for transportation, crating, handling, insurance, and sales taxes (where applicable) are due upon delivery of system.

Finance charges will be applied at the rate of 1.75% per month (21% per year), $5.00 minimum, on all Past Due balances.

DELIVERY:

It is estimated that shipment will be made within **120 days** after acceptance of the order, in writing, by BSD Medical Corporation.

TRANSPORTATION AND RISK OF LOSS:

All prices are F.O.B., Salt Lake City, Utah. All shipments will be shipped via best available carrier. Title, right to possession, and risk of loss pass at point of shipment.

SALES TAX:

Any applicable sales taxes will be added to invoice, unless proper Tax Exempt Numbers are provided with the order.

WARRANTY:

BSD Medical Corporation warrants this system to be free from defects in material and workmanship under NORMAL use and service for a period of **one year (twelve months)** after complete system installation. This warranty covers the entire system with the following limitations:

Consumable items are not covered. All thermometry probes and interstitial applicators (as applicable) are warranted at the time of installation only. Further repairs or replacements are limited to a maximum of **four (4)** each thermometry probes and a maximum of **four (4)** each interstitial applicators as they are considered to be consumable.

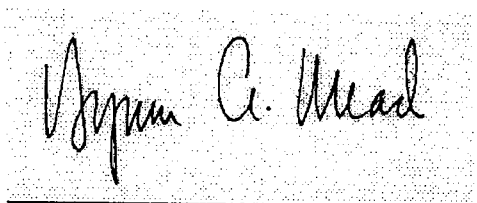
BSD Medical Corporation shall not be liable for consequential or incidental damages resulting from the failure or malfunction of its systems. BSD Medical Corporation makes no warranty for products modified by the buyer, or subjected to misuse, neglect, or accident.

BSD Medical Corporation does not warrant that our equipment will perform or operate according to specifications in conjunction with equipment and applicators not supplied by BSD Medical Corporation or in configurations not covered in our labeling.

This quote also includes a One-Year Type I Service Contract following the warranty period.

Standard Equipment and Options		Contract Price
BSD-500 Hyperthermia System		$282,575.00
	Sub-Total:	
Shipping Costs: *Transportation, Crating, Handling, Insurance*		$3,000.00
Plus Tax if applicable		
	TOTAL AMOUNT:	

BSD MEDICAL CORPORATION:



Signature

President
Title

December 8, 2005
Date

ACCEPTED BY:

Signature

Title

Date

ATTACHMENT 4: ORTHOVOLTAGE RADIOTHERAPY SYSTEM

XMS

Radiation Therapy
Equipment & Services

PRICE QUOTATION 06-0105A

January 5, 2006

Debra Lansey, MPA
Assistant Director, Health Policy Dept.
American Society for Therapeutic Radiation and Oncology
12500 Fair Lakes Circle, Suite 375
Fairfax VA 22033

THIS QUOTE IS VALID FOR 30 DAYS
Payment Terms: 25% deposit with order, 60% prior to ship, 15% upon completion of installation
Ship via: Best Way
FOB POINT: Bethel, CT USA
Gulmay standard warranty and terms and conditions are incorporated by reference

ITEM	DESCRIPTION	QUANTITY	PRICE	EXT.
1	D3300 Superficial X-Ray Therapy System			
	Dose Control	**1**	**$ 251,450.00 USD**	
	Time Control	**1**	**$ 239,850.00 USD**	

Consisting of:

- TP1 Controller and Monitor
- Dose Control
- PSD800 Distribution Box
- CP160 Cathode HT Generator
- CP160 Anode HT Generator
- Comet MXR321 Metal Ceramic X-Ray Tube Assembly
- Oil to Air Cooler/Oil to Water Cooler
- 2 X HT Cables
- Low Voltage Interface Cables
- Ceiling Mounted X-Ray Tube Support
- 9 Treatment Filters Plus Run Up Filter
- 4 X 30 cm FSD Open Ended Applicators
  - 3.0, 4.0, 5.0, 10.0 cm Diameter
- 6 X 50 cm FSD Close Ended Applicators
  - 4X4, 6X6, 8X8, 10X10, 15X15, 20X20 cm
- Operators Manual
- Technical and Physics Manual Complete with schematics

XMS

Radiation Therapy
Equipment & Services

Options:

Patient Verification System **$ 13,625.00 USD**
Includes the following modules and hardware:
1. System Administration
2. Treatment Module
3. Print Options
4. PC, Monitor and Printer

Floor Mounted Tube Stand **Reduce By: $ 8,700.00 USD**
In place of ceiling mounted tube support.

Installation includes the following (USA & Canada Only):

1. Uncrating.
2. Assembly of the equipment
3. Interface wiring.
4. Testing.
5. Customer acceptance testing as per Gulmay documentation. (Anty additional testing required by the customer to form part of the acceptance procedure must be agreed to in advance).
6. Physics and Operator familiarization. (Maximum two days).

With floor mounted x-ray tube support. **$ 13,000.00 USD**

With ceiling mounted x-ray tube support **$ 15,300.00 USD**

Notes:
1. One year parts warranty, one year prorated tube warranty.
2. Room preparation and power requirements are the sole responsibility of the hospital unless otherwise stated in the quotation. XMS will provide technical assistance to the hospital architects and engineers upon request.
3. Any delays or waiting as a result from room preparation on-site will be an extra dead time charge of $ 125.00 per hour per engineer + expenses.
4. Applicable sales tax is extra.

Tim Heflin
Authorized Signature

rec'd 1/4/06
4:08 PM

ASTRO
AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

January 3, 2006

VIA COURIER

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Re: CMS-1502-FC Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

Dear Dr. McClellan:

The American Society for Therapeutic Radiology and Oncology, Inc. (ASTRO) [1] appreciates the opportunity to provide written comments on the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, published in the *Federal Register* as a final rule with comment, on November 21, 2005. Our comments will address the (1) practice expense (PE) methodology; (2) the establishment of interim work relative value units for New CPT® Codes; (3) supply and equipment items needing specialty input; (4) the proposed multiple procedure reduction for diagnostic imaging; (4) the sustainable growth rate (SGR); and (5) recent Congressional actions on physician payment.

Resource-Based Practice Expense (PE) RVUs

1. Supplemental PE Surveys (70 Fed. Reg., 70132)

ASTRO is disappointed by CMS' decision to not implement the supplemental survey data submitted by ASTRO. In early 2004, ASTRO submitted a supplemental PE survey to CMS for use in the calculation of PE relative value units (RVUs) under the 2005 fee schedule. The survey was conducted because the practice expense per hour (PE/hr) of $66.80 used by CMS under the current top-down methodology is inaccurate and inconsistent with the actual costs of maintaining a radiation oncology practice.

[1] ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.

12500 Fair Lakes Circle
Suite 375
Fairfax, VA 22033
p 800.962.7876
703.502.1550
f 703.502.7852

We supported the CMS proposal to blend the data from our survey with the data submitted by the Association of Freestanding Radiation Oncology Centers (AFROC) to calculate a revised practice expense per hour (PE/hr) of $138.00 that is comparable to the results obtained from our own survey. This amount is more than double the PE/hr figure used by CMS in 2005. Consequently, by not using the more accurate survey data, the PE RVUs assigned to radiation oncology services will continue to be underpaid in 2006.

In the final rule, CMS stated that an error in the indirect PE program resulted in the publication of incorrect PE RVUs for almost all of the codes listed in the August 8, 2005 proposed rule. Therefore, CMS was concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology and were not given the sufficient opportunity to submit meaningful comments on the proposal. We understand that CMS needs to comply with the requirements of the Administrative Procedure Act; however, we do not understand why the proposal needs to be delayed for a full year.

CMS regulations established the use of survey data to determine PE RVUs. Having met the CMS requirements, we do not believe the agency can simply ignore the survey data that took considerable time and expense for ASTRO to collect. ***We recommend that CMS correct the error in the indirect PE program, publish a new proposed rule and implement a new final fee schedule for 2006 as soon as possible in Calendar Year 2006. At a minimum, we believe that CMS should make a commitment to use our survey data in the 2007 physician fee schedule.***

2. Changes in PE Designations (70 Fed. Reg., 70148)

In our comments on the proposed rule, we identified several radiation oncology related services that are assigned the designation "NA" in the 2006 proposed rule. We asked that CMS list the RVUs for these codes in the final rule so that it would be clear that payment is not precluded in the non-facility setting. The codes we identified were:

CPT® Code	Description
19297	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)
31643	Bronchoscopy, rigid or flexible; with placement of catheter(s) for intracavitary radioelement application
43241	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with transendoscopic intraluminal tube or catheter placement
57155	Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy
58346	Insertion of Heyman capsules for clinical brachytherapy
76001	Fluoroscopy, physician time more than one hour, assisting a non-radiologic physician (eg, nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy)

We acknowledged that these services are infrequently performed in a non-facility setting relative to the facility setting. However, there are circumstances when existing CMS payment policy would permit payment. For example, partial mastectomies are on the list of covered ASC procedures but CPT® Code 19297; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure),* is not. In accordance with CMS policy, a procedure performed in an ASC that is not on the list of covered procedures can be paid but payment is at the non-facility rate. Unfortunately, the "NA" designation is often interpreted to mean that payment for a procedure with this designation will not be made.

We appreciate CMS including a definition of the "NA" designation in the preamble of the final rule. Previously, an "NA" indicated a procedure that is "rarely or never" performed in the non-facility setting. In the final rule, the designation is described as a service for which CMS has not developed a PE RVU in the non-facility setting because it is typically performed in the hospital.

We also appreciate CMS removing the "NA" designation for CPT® Code 76001; *Fluoroscopy, physician time more than one hour, assisting a non-radiologic physician (eg, nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy).* However, the five remaining codes continue to be designated as "NA." In the final rule, CMS noted that all of the requests they received to establish PE RVUs in the non-facility setting were for services where non-facility inputs had not been developed by the PEAC/RUC. CMS recommended that all specialty societies follow the long standing RUC process for the establishment and refinement of PE inputs. We agree and we will help other specialty societies develop non-facility inputs for the CPT® Codes we have identified.

In the interim, we believe it would be helpful for CMS to expand the definition of "NA" to clarify that procedures so designated will be paid based on the facility PE RVUs if the physician determines, on a case-by-case basis, that the procedure can be safely performed in a non-facility setting. This expansion of the definition would be consistent with existing CMS policy and it would remove the incorrect perception that payment for procedures with the "NA" designation cannot be made.

Establishment of Interim Work Relative Value Units for New CPT® Codes (70 Fed. Reg., 70275)

ASTRO would like to thank CMS for accepting our recommendations regarding the work relative value units for the new radiation oncology CPT® Code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy*, with an interim work RVU of 0.39. The rationale behind the new CPT® Code is that stereoscopic x-ray guidance allows radiation oncologists to be able to more accurately ensure that the target volume is treated to the planned dose of radiation. Since the tumor target volume mapped for 3D or IMRT may vary on a daily basis depending on errors in setup and internal motion of the target volume or surrounding tissues, stereoscopic X-ray guidance effectively detects and allows corrections of deviations between actual and planned target position. Locating the target volume on orthogonal X-rays with fiducial markers (when target volumes cannot be well seen on X-rays) or without them (if the target volume can be seen on X-rays) ensures accurate treatment of the target and spares unnecessary radiation of normal tissue.

We also appreciate CMS agreeing with the RUC recommendation for CPT® Code 77422; *High energy neutron radiation treatment delivery; single treatment area using a single port of parallel-opposed ports with no blocks or simple blocking* (PE RVU 1.71) and CPT® Code 77423; *High energy neutron radiation treatment delivery; 1 or more isocenter(s) with coplanar or non-coplanar geometry with blocking and/or wedge, and/or compensator(s)* (PE RVU 2.26), both with interim work RVUs of 0.00.

In the final rule, CMS recognized that the equipment for CPT® Codes 77332 (treatment devices, simple) and 77333 (treatment devices, intermediate) was missing. We are thankful that CMS changed the practice expense (PE) database to reflect the accurate costs involved, crosswalking the expenses to CPT® Code 77334. We understand that these codes are priced in the nonphysician work pool (NPWP) and look forward to the time when CMS accepts the supplemental survey data and eliminates the NPWP to allow for direct inputs to be used to establish practice expense RVUs for the NPWP services.

Supply and Equipment Items Needing Specialty Input (70 Fed. Reg., 70140)

We are responding to your request that specialty groups provide the necessary pricing information, including appropriate documentation, for several radiation oncology items. More specifically, we have reviewed Table 14: Supply Items Needing Specialty Input for Pricing, and Table 15: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions. From Table 14, there was one supply item we identified relating to radiation oncology, as well as three equipment items listed in Table 15 that need price information. **We will provide documentation per this request, including a list of price quotes for each of the items, and additional backup material (i.e., copies of invoices or catalog with pricing information) in a separate letter.** The supplemental letter will maintain confidentiality of those who provided ASTRO with this documentation.

Due to office schedules during the holidays, we have experienced difficulty obtaining pricing information for some items on which we wish to comment. CMS has granted us a short extension for submitting pricing information. Upon receipt of this information, ASTRO will forward the prices and documentation for the following items: Sealant spray (CMS Supply Code SL119); hyperthermia system, ultrasound, intracavitary (CMS Equipment Code ER036); orthovoltage radiotherapy system (CMS Equipment Code ER045); and OSHA ventilation hood (CMS Equipment Code ER008). We thank you for your patience in this matter.

We strongly request that CMS maintain these radiation oncology items proposed for deletion as they remain necessary items for the practice of radiation oncology. It is imperative that radiation oncologists receive reimbursement for these items in order to maintain essential treatments for their patients.

Multiple Procedure Reduction for Diagnostic Imaging (70 Fed. Reg., 70261)

CMS proposed to extend the multiple procedure payment reduction to the technical component (TC) of global services in 11 families of imaging procedures by imaging modality ultrasound, CT and computed tomographic angiography (CTA), MRI and magnetic resonance angiography (MRA) and contiguous body area (for example, CT and CTA of Chest/Thorax/Abdomen/Pelvis). Under this

proposal, when multiple procedures within the same family are performed in the same session, CMS would make full payment for the TC of the highest priced procedure and payment at 50 percent of the TC for each additional procedure.

In the final rule, CMS adopted its proposal but indicated that there will be a 2 year phase-in, with a 25 percent payment reduction applied in 2006 and a 50 percent reduction in 2007. We believe there has been insufficient study of the actual reduction in practice expense when multiple procedures are performed on a given patient during a single diagnostic session. Furthermore, it may be that different families of services have different levels of savings. No consideration has been given to the affect on studies done for diagnostic compared to therapeutic planning. For example, imposing an across the board cuts may adversely affect some services in unexpected ways. ***We believe that CMS should take more time to closely examine the impact for each category of imaging families and work with ASTRO, the American College of Radiology (ACR), and the Relative Value Update Committee (RUC) to determine what percent payment reduction is appropriate. We suggest there be an additional 1 year delay before implementation of any reduction in reimbursement to allow practices to prepare for the change.***

The Update Adjustment factor and the Sustainable Growth Rate (SGR) (70 Fed. Reg., 70301)

Updates to Medicare physician payments are made each year based on a statutory formula established in section 1848(d) of the Social Security Act. The calculation of the Medicare physician fee schedule update utilizes a comparison between target spending for Medicare physicians' services and actual spending. The update is based on both cumulative comparisons of target and actual spending from 1996 to the current year, known as the Sustainable Growth Rate (SGR), as well as year-to-year changes in target and actual spending. The use of SGR targets is intended to control the growth in aggregate Medicare expenditures for physicians' services.

In our comments, we described the flaws in the SGR formula that led to a 5.4% payment cut in 2002. Additional cuts in 2003 through 2005 were averted only after Congress intervened. The Medicare Trustees project that physicians and other health professionals face steep pay cuts (about 26%) from 2006 through 2011.

Consistent with the position of the American Medical Association (AMA), we identified several steps that should be taken that would significantly reduce the costs associated with a permanent legislative fix to the Sustainable Growth Rate (SGR) formula. Most importantly, we recommended that CMS remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

We were extremely disappointed that CMS continues to believe it does not have the authority to make this change. In the final rule, CMS announced a 4.5 percent reduction in the 2006 conversion factor from $37.8975 in 2005 to $36.1770 in 2006. If these cuts begin on January 1, 2006, average physician payment rates will be less in 2006 than they were in 2001, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service. Physicians simply cannot absorb these severe payment cuts and, unless CMS or Congress acts,

physicians will be forced to reevaluate their relationship with Medicare and will be forced to avoid, discontinue or limit the provision of services to Medicare patients.

Recent Congressional Action on the Physician Payment Reduction

In early December 2005, the US House of Representatives passed a budget package that affects reimbursement to radiation oncologists. The budget enables a one-year freeze on CY2006 Medicare physician payments at the CY2005 payment levels. The bill also includes a change to the Medicare payments for imaging services. The reimbursement for the technical component of imaging services would be limited to no more than the payment for the same service under the outpatient hospital prospective payment rate.

ASTRO is currently working to assure that radiation treatment planning, simulation and delivery codes are specifically not included as imaging services in the bill. ASTRO believes that the legislative proposal is arbitrary and harmful to cancer patients whose access to imaging services is essential to their treatment.

The budget package also would limit payments for surgical procedures done in ambulatory surgical centers (ASCs) to the ambulatory payment classification (APC) rates paid to hospital outpatient departments (under the hospital outpatient prospective payment system, or HOPPS). ASTRO does not support paying services performed in ASCs using APC rates because the hospital outpatient department setting is sufficiently different than the ASC setting and would therefore require an independent cost analysis.

Conclusion

Thank you for this opportunity to comment on this proposed rule. We look forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Ms. Trisha Crishock, MSW, Director of ASTRO's Department of Health Policy, by telephone at (703) 502-1550 or by e-mail at trishac@astro.org.

Respectfully,

Laura Thevenot

Laura Thevenot
Chief Executive Officer

cc: Herb Kuhn
Kenneth Simon, M.D.
Edith Hambrick, M.D.
Rick Ensor
Ken Marsalek
Pam West
Trisha Crishock, M.S.W.

43 Rec'd 1/4/06
4:24 pm

ALSTON&BIRD LLP

601 Pennsylvania Avenue, N.W.
North Building, 10th Floor
Washington, DC 20004-2601

202-756-3300
Fax: 202-756-3333
www.alston.com

Peter Kazon
Direct Dial: 202-756-3334
E-mail: peter.kazon@alston.com

January 3, 2006

HAND DELIVERY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS: 1502-FC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Sir or Madam:

On behalf of the American Clinical Laboratory Association, please find enclosed comments on the Final Physician Fee Schedule for Calendar Year 2006. If you have any questions or comments, please do not hesitate to contact us.

Sincerely,

Peter Kazon

PK:caj
Enclosures

WDC01/226196v1

Comments of the
American Clinical Laboratory Association
on the
Final Physician Fee Schedule for Calendar Year 2006
[CMS–1502–FC]

American Clinical Laboratory Association

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the Final Physician Fee Schedule Rule that was published November 21, 2005 (70 Fed. Reg. at 70116 ("Final Rule"). ACLA is an association representing independent clinical laboratories throughout the United States, including local, regional and national laboratories. ACLA members employ and contract with physicians who perform physician services reimbursed under the physician fee schedule. Thus, ACLA members will be significantly affected by the changes in the Final Rule.

As CMS is aware, ACLA has been working with CMS concerning changes that were made in 2004 relating to flow cytometry payment. ACLA submitted additional information concerning the costs of performing the technical component of these services, which affected CMS' calculation of the Practice Expense for these services. In the Final Rule, CMS states in response that it appreciates the support extended by ACLA and other organizations and that the changes in the PE values have been made to the database. *Id.* at 70138. However, because of errors made by CMS in the calculation of indirect practice expense for all physician services, CMS did not implement any changes to PE values in the new fee schedule. *Id.* at 70132.

ACLA is deeply disappointed that while the practice expense amounts have been "accepted in the database," they have not actually been implemented. It is especially difficult in this situation because the new flow cytometry codes were not announced until last year's Final Physician Fee Schedule; thus, there was no opportunity to comment on these changes until after they were already effective. This is the first opportunity that CMS has had to make any changes to the values for these codes. As a result, CMS should correct these errors, and ACLA looks forward to continuing to work with CMS to resolve this issue.

Thank you for the opportunity to comment. If you have any further questions or comments, please do not hesitate to contact us.

1250 H Street, N.W. • Suite 880 • Washington, DC 20005 • (202) 637-9466 Fax: (202) 637-2050

American College of Radiation Oncology
5272 River Road • Suite 630 • Bethesda, MD 20816
(301) 718-6515 • FAX (301) 656-0989 • EMAIL acro@paimgmt.com

January 3, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington D.C. 20201

Re: Final Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B (42 CFR Part 405) – File Code CMS-1502-FC

Dear Dr. McClellan:

The American College of Radiation Oncology ("ACRO") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Final Rule regarding Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006.[1] Founded in 1989 with a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology.

ACRO commented extensively on the proposed regulations[2] and CMS included much of ACRO's observations in the Final Rule. In several sections, CMS requested that ACRO work with CMS staff to further discuss concerns. Specifically, CMS requested additional discussion with ACRO regarding the following:

- ACRO's belief that the "bottom up" methodology and the translation of basic inputs into relative weights may unintentionally compress higher-cost technology; and
- The method by which the blending of the AFROC and ASTRO surveys would underweight the practice expense for freestanding facilities and overestimate the denominator in the PE/HR calculation.

[1] CMS-1502-FC and CMS-1325-F, *Federal Register*, November 21, 2005, Vol. 70, page 70116.
[2] CMS-1502-P, *Federal Register*, August 8, 2005, Vol. 70, page 45764.

We appreciate the interest that CMS has shown and look forward to future discussions on these and other issues. To facilitate this process, we have asked Andrew Woods, our legal counsel, to contact your staff and arrange a time to meet.

ACRO is committed to ongoing involvement with the American Medical Association's Specialty Society Relative Value Update Committee (RUC). Our efforts support assuring that the full continuum of resources needed to provide each specific radiation oncology service are appropriately included in the RVU calculations. In addition, we continue to be concerned that select brachytherapy nonfacility practice expense RVUs should reflect the associated higher practice expenses and not default to the facility practice expense RVUs. ACRO would also welcome the opportunity to give further input on the appropriate level of both work and practice expense RVUs for 19298, Placement of radiotherapy afterloading brachytherapy catheters, interstitial tube and button catheters.

We understand your plan to delay the revisions to the practice expense RVUs and would appreciate the opportunity to give further input about the survey data and the methodology. The delay makes it imperative that the -4.3% sustainable growth factor be rescinded. In addition, it is important to recognize that a number of specialties, radiation oncology included, took the time and effort at significant expense to submit supplemental surveys. For radiation oncology, the supplemental survey process clearly indicated that CMS's current PE/HR dramatically underestimates the actual expenses incurred in providing radiation oncology services.

It is important to note that many of the members of ACRO participated in the survey processes sponsored by ASTRO and AFROC. ACRO would like to express its appreciation for the time and effort that radiation oncologists spent on the survey process.

Radiation oncology is also potentially affected by the multiple imaging discounts and the reductions in reimbursement to freestanding centers for certain radiology procedures. ACRO is particularly focused on the reimbursement reductions proposed for imaging studies that play a critical role in treatment planning. We are concerned about the impact on access to care for our cancer patients, since we do not believe that this budget change sought to impact cancer care. We suggest that you delay the imaging discount process for at least one year until the matter can be more carefully studied.

In summary, we appreciate the opportunity to comment on these important rulings and we are interested in having further discussions with the agency. We look forward to meeting with CMS representatives in the near future.

Sincerely,

D. Jeffrey Demanes, M.D.
President
American College of Radiation Oncology
5272 River Road
Suite 630
Bethesda, Maryland 20816

Sincerely,

Michael Kuettel, M.D.
Chair, Socioeconomics Committee
American College of Radiation Oncology
5272 River Road
Suite 630
Bethesda, Maryland 20816

45 rec'd 1/4/06
4:05 pm

LIGAND
PHARMACEUTICALS

By Hand Delivery

January 3, 2006

Mark B. McClellan M.D. Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-1502-FC and CMS-1325-IFC3 (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B)

Dear Dr. McClellan:

Ligand Pharmaceuticals is pleased to submit comments on the Interim Final Rule with Comment Period (the "Interim Final Rule", 70 Fed. Reg. 70116 (Nov. 21, 2005). [CMS-1502-FC and CMS-1325-F] issued by the Centers for Medicare & Medicaid Services ("CMS") to implement the Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B. We appreciate this opportunity to share our views on this important component of the reforms included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").

Ligand is one of the leaders in oncology innovation, with a strong commitment to developing treatment options for rare cancers and improving patient lives. In keeping with this commitment, Ligand manufactures Ontak, which is reimbursed under Medicare Part B. Based on our reading of the Interim Final Rule, and that of the Interim Final Rule Related to Physicians Services 70 Fed. Reg. 70469 (Nov. 21, 2005). [CMS-1502-FC] Ontak will not be included in the Competitive Acquisition Program ("CAP"); this is the subject of our comments herein. We support the development and implementation of the CAP in a manner that provides open access to all Part B drugs and ensures continuity of patient care.

LIGAND PHARMACEUTICALS INC., 10275 Science Center Drive, San Diego, CA 92121-1117 (858) 550-7500 fax (858) 550-7506

The following comments address the specific program design consideration at issue in this rule, and the subject of orphan products such as Ontak, knowingly being excluded from CAP.

1. Drugs Included under the CAP

A. CAP vendors should be required to provide orphan-designated products in order to assure appropriate patient access for products that may be a patient's only course of appropriate treatment

ONTAK, is a recombinant DNA-derived cytotoxic fusion protein that is a covered by Medicare under Part B in both the hospital outpatient setting and in the physician office. ONTAK received orphan designation from the FDA and is used to treat the limited population of patients with advanced stages of Cutaneous T-Cell Lymphoma (CTCL). Approximately 850 patients were treated with ONTAK in the past year and Ligand estimates less than 35% were covered by Medicare under Part B. CTCL is a rare cancer and while the prognosis for early stage patients is quite good with median survival of 12 years, later stage patients for whom ONTAK is an approved therapy and principally utilized have a median survival of 2.5-5 years. (Siegel R. JCO, Vol 18, No. 15, 2000 pp 2908-2925). Patients most often succumb to opportunistic infection and so selecting therapies that are less immuno/myelosuppressive is an important consideration. ONTAK is one of the very few therapies FDA approved for late stage CTCL. In addition, because it is less immuno/myelosuppressive than available chemotherapies it is often the patient's only hope of a response to this aggressive disease.

Ligand believes that orphan drugs and biologicals should not be excluded categorically from the CAP, but rather, that they should be categorically included. Orphan products are the very therapies that should be included to ensure patient access. Therefore, all orphan drugs which are provided in the physician's office under Medicare Part B should be included in the CAP program. Contrary to the current program where the orphan product must be approved and added by a vendor we believe the vendor should have to positively affirm a specific rationale for keeping such products off of CAP formularies. Ligand Pharmaceuticals specifically requests that CMS add Ontak (denileukin diftitox - J9160) to the category of products to be made available via the CAP at the inception of the program which is currently planned for July 2006. Because demand for orphan drugs, like ONTAK, is extremely low and variable, they are costly to manufacture and costly for physicians to keep in inventory. The CAP will therefore, we believe, improve access to this important therapy.

As we have previously commented to other CMS proposed regulations, physician feedback received by Ligand has indicated that in some cases, acquisition cost has exceeded reimbursement under the ASP+6% methodology. This has resulted in an un-due influence on the site of medical practice by shifting patients from the physician offices to the hospital outpatient sites based on the current reimbursement rate structure. This situation is exacerbated by imposing similar methodology in the Hospital Outpatient Prospective Payment System. Including ONTAK in the CAP will serve to rectify this imbalance and improve patient access, particularly in small and rural practices.

II. **CAP Bidding Process**

A. Manufacturer prices made available under the CAP should not be included in the calculation of average sales price (70 Fed. Reg. 70478)

Ligand supports the exclusion of manufacturer prices made available under the CAP in the calculation of ASP and requests that CMS confirm that manufacturer prices made available under the CAP should not be included in the calculation of ASP in the Final Rule We agree with CMS' rationale for exclusion and note that in the case of Ontak where we may be forced to concede certain price concessions as a result of CMS' attitude towards orphan products that ASP exclusion still meets the overriding legislative goal of a reflection of market pricing because in an open market our pricing and actions would be different than what CMS' forces us to do under CAP as a result of having an orphan product.

B. Manufacturer prices made available under the CAP should be exempt from best price under Medicaid (70 Fed. Reg. 70479)

Ligand encourages CMS to review arguments in support of the exclusion of manufacturer prices made available under the CAP in the calculation of "best price" for purposes of Medicaid and believes such a policy is in keeping with the Medicare Modernization Act (MMA) and the intent of the Congress. Exemption from Medicaid best price, especially in a situation where orphan products are almost certainly forced to make price concessions which under normal circumstances would drag down a product's ASP and affect its Medicaid best price, is an appropriate policy for Medicare to follow.

III. Clarification Requests

A. CMS should provide guidance in the Final Rule regarding what will constitute "bona fide" services in the fee-for-service arrangements between CAP vendors and manufacturers

Ligand requests that CMS provide guidance in the Final Rule concerning the types of "bona fide" services CAP vendors will be permitted to provide manufacturers in exchange for administrative fees. Specifically, Ligand would like CMS to provide guidance on the classification of services such as prompt payments, inventory management and storage, distribution, data collection, chargeback management, deduction management, membership fees, consolidation of distribution fees and case management services including compliance and medication management programs. Many services that were previously performed by distributors as part of the distribution service are now being offered as separate services by CAP vendors. CMS should specifically outline to manufacturers what it considers to be "bona fide" services and therefore excluded from ASP calculation so long as they do not get passed on to physicians and ultimately affect the price actually realized by the CAP vendor.

Again, Ligand appreciates the opportunity to share our views on this important regulation. We look forward to working together to implement the CAP in a way that promotes high quality care for Medicare beneficiaries while improving the administration of the Medicare program. Please do not hesitate to contact me at (858) 550-7569 or by electronic mail at tghio@ligand.com if you have any questions or need further information about these comments.

Sincerely,

Terese M. Ghio
Vice President
Government Affairs & EH&S
Ligand Pharmaceuticals

46 rec'd 1/4/06

KING & SPALDING LLP

1700 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706
www.kslaw.com

Laura E. Loeb
Direct Dial: 202-661-7836
LLoeb@kslaw.com

January 3, 2006

BY EMAIL

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Room 445-G
Washington, D.C. 20201

RE: CMS-1502-FC; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Section III D

Dear Administrator McClellan:

On behalf of the University of Pittsburgh Medical Center (UPMC), we are respectfully submitting comments on Section III D of the Final Rule for the Medicare Physician Fee Schedule for 2006. Specifically, our comments are limited to the creation of new codes in the 2006 Fee Schedule (CPT codes 76376, 76377) that omit the work involved in the creation of 2D Multiplanar Reformatted (MPR) images. These 2D MPR images serve a very important patient care role, and the work and time involved in producing these images is separate and distinct from that required for the underlying procedure.

While the technology does exist to provide these images more automatically, requiring little additional work, the equipment is very expensive and is not widely dispersed currently. UPMC does not believe the technology is currently so widely available, particularly in rural areas, that there should be no code available in 2006 to describe the traditional 2D reformatting procedure that does require additional time. Therefore, UPMC urges CMS to create an interim G-code as soon as possible to describe this clinically valuable 2D service that is currently being provided and that requires additional time, until the new automated technology is more widely available.

Background

For the 2006 CPT codes, the American Medical Association (AMA) deleted code 76375, "Coronal, sagittal, multiplanar, oblique, 3-dimensional and/or holographic reconstruction of computed tomography, magnetic resonance imaging, or other tomographic modality". This code

included both 2D and 3D reformatting. We understand that CMS was going to propose a new Correct Coding Initiative (CCI) edit that would not have allowed separate reimbursement for 76375 in most, if not all, cases, because CMS believed that minimal additional work was required for this reformatting.

Therefore, for 2006, CPT code 76375 was deleted by the AMA. The AMA did create for 2006 new CPT codes that describe 3D reformatting -- CPT codes 76376 and 76377. However, this has resulted in no CPT code existing for 2D reformatting in 2006.

Continuing Clinical Value of 2D Reformatting

The ability to create additional 2D images from an original CT scan acquisition data set is essential in making the most concise diagnostic interpretation. Although new technology permits this process to be performed automatically as part of an exam protocol, most of the existing installed base of equipment, even within a tertiary care center such as UPMC, lacks this sophistication. Of the eight CT scanners available at UPMC, only one has the ability to automatically perform this function. The sequential replacement of the current installed base of equipment will take approximately seven years. UPMC does not believe it is unique with respect to this issue. Providers, particularly in rural areas, will still have expensive 2D reformatting equipment with significant useful life that CMS is forcing to become obsolete by deleting any available coding options.

These 2D MPR images provide a very important clinical service. For example, during a post-trauma scan, images acquired in an axial plane alone may very likely miss a fracture visible in a coronal view. This lack of diagnostic information could lead to further complications of an unappreciated spinal cord injury resulting in paralysis. Routinely, MPR images are created for protocols including temporal bones, sinuses, face, orbits, upper and lower extremities, as well as cervical, thoracic, and lumbar spine images.

Additional Work Involved with 2D Reformatting

Creating the MPR images takes approximately 15 additional minutes on all but one of the eight UPMC scanners. This is additional time above and beyond the original data acquisition set. This additional time would apply to all facilities that currently operate with CT scanners of all speeds with the exception of the most advanced, expensive 64-slice equipment. While market deployment of the 64-slice scanners is proceeding throughout the industry, most facilities will continue to use older generation scanners to perform a great percentage of studies. These older generation scanners still provide quality, clinically useful images.

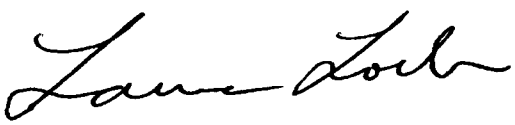
Conclusion

Thus, the exclusion of 2D reformatted images (coronal, sagittal, multiplanar, oblique) from the 2006 CPT codes will not only have a very negative financial impact on institutions without the most advanced scanner, but will also significantly hinder patient care. This impact will continue until the existing installed equipment base is replaced, which is a very expensive project that most institutions cannot accomplish overnight, as CMS appears to envision. While 2D images are not as complex to produce as 3D reconstructions, there is still additional work and time involved with these 2D reformatted images on all but the most advanced 64-slice equipment.

This time and work should be recognized until the 64-slice scanners are more widely dispersed throughout the country. Therefore, UPMC strongly urges CMS to create a temporary G-code to describe this valuable clinical service.

UPMC representatives would be happy to answer any further questions CMS staff might have regarding this issue and to work with CMS staff to swiftly resolve this problem.

Respectfully submitted by,



Laura Loeb
Partner